“EFFICACY OF TOPICAL IVERMECTIN IN COMPARISON TO OTHER SCABICIDAL AGENTS”

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(BRANCH XX)

MADRAS MEDICAL COLLEGE

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CHENNAI

APRIL 2017

CERTIFICATE

Certified that this dissertation titled **"EFFICACY OF TOPICAL IVERMECTIN IN COMPARISON TO OTHER SCABICIDAL AGENTS"** is a bonafide work done by **Dr.R.RAJALAKSHMI,** Post graduate student of the Department of Dermatology, Venereology and Leprosy, Madras Medical College, Chennai – 3, during the academic year 2014 – 2017. This work has not previously formed the basis for the award of any degree.

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DECLARATION

The dissertation entitled **"EFFICACY OF TOPICAL IVERMECTIN IN COMPARISON TO OTHER SCABICIDAL AGENTS"** is a bonafide work done by **DR.R.RAJALAKSHMI** at Department of Dermatology, Venereology and Leprosy, Madras Medical College, Chennai – 3, during the academic year 2014– 2017 under the guidance of **Professor Dr. U R DHANALAKSHMI, M.D.,** Professor, Department of Dermatology, Madras Medical College, Chennai -3. This dissertation is submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai towards partial fulfillment of the rules and regulations for the award of M.D Degree in Dermatology, Venereology and Leprosy (BRANCH – XX)

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DECLARATION

I, **DR.R.RAJALAKSHMI** solemnly declare that this dissertation titled **"EFFICACY OF TOPICAL IVERMECTIN IN COMPARISON TO OTHER SCABICIDAL AGENTS"** is a bonafide work done by me at Madras Medical College during 2014-2017 under the guidance and supervision of **Prof.U.R.DHANALAKSHMI, M.D., D.D., D.N.B. (DVL),** Professor and Head, Department of Dermatology, Madras Medical College,Chennai-600003. This dissertation is submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai towards partial fulfillment of the rules and regulations forthe award of M.D Degree in Dermatology, Venereology and Leprology. (BRANCH – XX).

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INTRODUCTION

INTRODUCTION

Scabies has been a major health problem in many countries worldwide because of its very high prevalence. The estimated prevalence varies from 0.2 to 71 %.[1] Nearly hundred million people are affected worldwide.

It affects people of all races and social classes.[2] It spreads rapidly in crowded conditions.[2] Institutions like nursing homes, prisons and extended care facilities are often sites for outbreaks of scabies.

It is a common, intensely pruritic dermatosis, caused by the mite *Sarcoptes scabiei var hominis.* It is highly contagious & transmitted by close, skin to skin contact [3.] For atleast 3000 years it has been a very common disease.

Scabies remains a major problem in terms of its contagious nature and the secondary infections which occur as a result of the disease.In our study, we are comparing the use of GBHC, Permethrin and Topical Ivermectin for the treatment of scabies. In addition, the epidemiological patterns of the disease were ascertained. So, these study findings will play an important role to determine the effective drug for patients with scabies.

REVIEW OF LITERATURE:

The word scabies is derived from Latin term *Scabere* which means 'to scratch'[4,2]. Scabies known by various names like Family itch , 7 year itch, camp itch, Norwegian itch, Bonomo's disease, Acariasis. It is referred to as Sarcoptic Mange in animals and Scaly leg in birds[4].

HISTORY:

The history of discovery of the agent causing scabies is fascinating.[5]

- Aristotle (384-322 BC), was the first to use the term 'akari' to designate a wood-dwelling mite.[6]
- Giovan Cosimo Bonomo together with Diacinto Cestoni discovered the etiologic agent in 1867[6]. They stated that it reproduced through male and female union, affirmed it laid eggs[6]. It was suggested mites could get transmitted by clothes and fomites.[7]
- Francesco Redi must be honoured as he was Bonomo and Cestoni's Master. Although he was not involved directly in discovery, he guided them and stimulated their work.[8]
- Bonomo was honoured for the discovery and first description of the Sarcoptes scabiei by Cumston in the year 1924.[9]
- Bonomo's signed letter was noticed by Razzauti in the Library of Fraternità di S. Maria of Arezzo Razzauti in the year 1927. [9]

REVIEW OF LITERATURE

- Avenzoar first described Scabies mite in 12th century in Spain but did not link it with the skin eruption which is associated [10].
- August Hauptmann was the first person to show the mite in 1654.
- In a letter to Franseco Redi in 1687, Giovanni Bonomo described and drew the mite.[11]
- Von Hebra in 1844 stated that scabies was local disease and not internal disease.[4]
- Mellanby in 1943 described the life cycle of the mite. [4]

Scabies is intensely pruritic and a highly contagious parasitic infestation. In the new millennium especially with HIV pandemic it is a re-emerging infection and a significant health problem in developing countries.[12,13]

EPIDEMIOLOGY:

Nearly hundred million people are affected worldwide. The major disease burden is by the developing countries due to poor sanitation and poor housing facilities. The disease is more prevalent in the very young, but it is also frequent in children and the young adults and thereafter the prevalence declines sharply. The disease is more frequent in autumn and winter. This may be because of the biological characteristics of the mite. Mites survive for a longer duration in the cooler weather. Mites may be sensitive to the human sweat which contains antimicrobial peptidethereby leading to reduced prevalence in the summer.

SCABIES MITE:

Sarcoptes scabiei var hominis, host specific mite causes human scabies. It is an obligate human parasite. It is a member of the

Class	:	Arachnida
Subclass	:	Acari
Order	:	Astigmata
Family	:	Sarcoptidae[14,15]

Nearly 15 different varieties or strains have been isolated from various hosts, but they are morphologically similar[17].Astigmata members are slow-moving mites. They have thinly sclerotized integuments and spiracles are not detectable[16,17]. It is a non-haematophagous mite.[18] The colour of the mite is creamy brown. It has brown sclerotised legs and mouthparts[17,19]. The adult female measures approximately 0.3 to 0.5 mm in length by 0.3 mm width whereas the male is slightly smaller measuring around 0.25 mm in length by 0.2 mm width[17]. Larvae are six legged and nymph and adults are eight legged[17]. Suckers are present in first and second legs in adult mites of both sexes. It enables them to grip the substrate[17]. In addition, mites possess spur-like claws and on their dorsal surfaces, have six to seven pairs of spine like projections. [17,19]

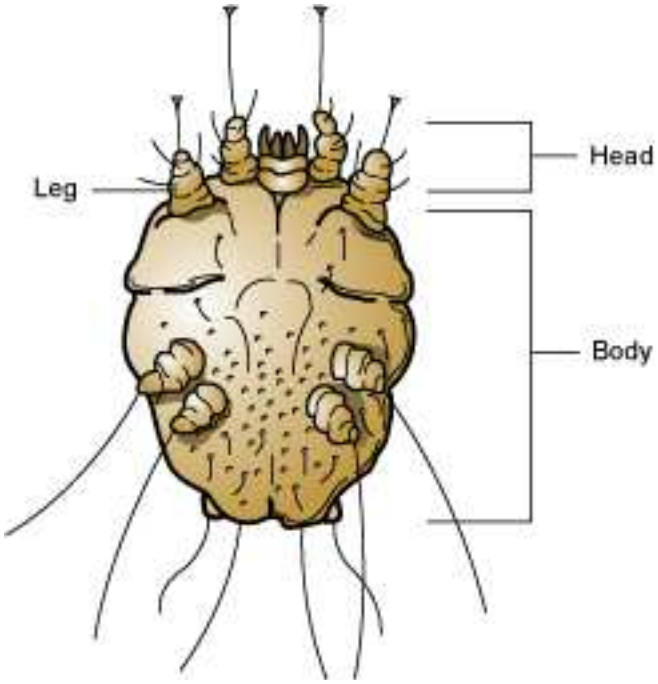


FIGURE 1- Dorsal view of scabies mite

Difference between male and female mite:[17]

ADULT MALE	ADULT FEMALE
Small size compared to female 0.25mm in length and 0.2 mm in width	Large size compared to male 0.3-0.5mm in length and 0.3 mm in width
Darker colour compared to female	Lighter colour compared to male
Presence of stalked pulvilli on 4th leg	Long setae in 4th leg

Death occurs rapidly above temperature of 55 _C. It can survive outside the host for 2–3 days.[20,24]

The adult mites crawl rapidly on the skin surface, with females travelling up to 2.5 cm/min (average speed 1 in/min). [2]

Life cycle of Sarcoptes scabiei:

Sarcoptes scabiei undergoes 4 stages in its life cycle; egg, larva, nymph and adult.[2]

Upon finding a favourable site, the female mite burrows into skin, and in about an hour completely disappears beneath the surface.[2] Mite secretes a saliva-like substance which dissolves skin and thereby helping in burrowing into the skin. Scabies mite burrows at the rate of 0.5-5mm per day[15]. Within these burrows, male and female mites mate.[2] After mating, the impregnated female excavates a burrow and lays eggs in it[2]. The female mite spends the rest of her life in the burrow which is commonly 30-60 days whereas the male mite dies. The length of the burrow will be continuously extended by female mite and it usually burrows a total length of 1 cm (~½ inch) or more.[2]

Developmental stages are

- Egg
- Larva
- Protonymph
- Tritonymph
- Adults[21]

The female mite begins to lay eggs producing 2 or 3 each day[2]. The eggs hatch in 3-4 days and within a day of hatching, the larvae begins to crawl actively out of the burrow towards the skin surface[2]. Larvae then excavate shallow burrows and feeds in them and molts to nymph after 3 days. The nymphs dig just beneath the surface where it molts to adults within 3-4 days[2].

The developmental time taken for the egg to develop intoadult takes about 10 days for males and 14 days for females.Male mites live for 1-2 days only and spend this time searching for female mite and dies after mating [22, 23]. In her life time, female mite may lay as many as 180 eggs. The eggs are mostly removed from skin by bathing, scratching, or rubbing of the skin[2]. Mites do not survive for more than 48-72 hours, once they are away from the human body[2].

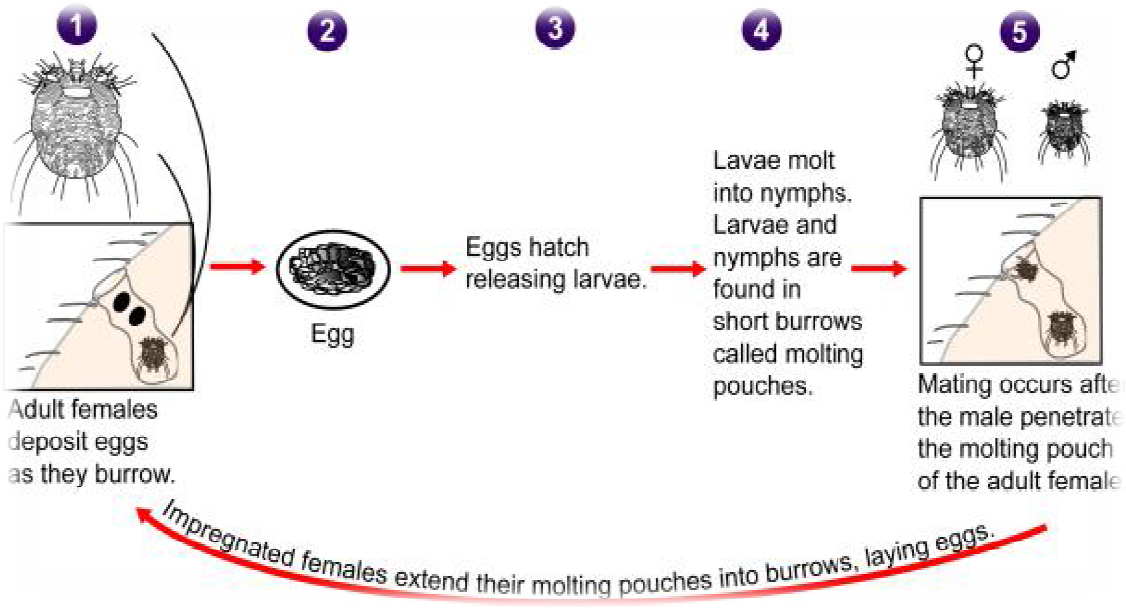


FIGURE 2 -LIFE CYCLE OF SCABIES MITE

MODES OF TRANMISSION :[2]

The most common method by which scabies is transmitted is by direct contact between the individuals when mites are crawling on the surface of the skin[2]. This contact must be direct skin-to-skin contact for the disease to be transmitted but a quick handshake or hug does not usually spread scabies. Because infestation often spreads during close physical contact of sexual

activity, it is sometimes considered as a sexually transmitted disease[2]. However, scabies mite is often usually passed from person to person in situations where people live in close contact, including hospitals, nursing homes, hostel, prisons, child care facilities, and institutions.[2]

The disease can also be transmitted via prolonged contact with bed linen and other clothing from infested hosts. If relative humidity is more than 30%, the mite survives for 2-3 days at room temperature. Inanimate objects that might be contaminated with infectious organisms and serve in disease transmission are fomites[2]. Mites may survive for up to 7 days in such inanimate objects. Indirect transmission through fomites is not common and usually only occurs if these inanimate objects are contaminated by infested hosts immediately beforehand[2].

A person is considered to be infectious from the moment of being infested until completion of treatment successfully. Linen and clothing are considered to be infectious until the completion of treatment or till two weeks after the last exposure. After treatment the patient may unknowingly become reinfested again through exposure to the primary source of infestation or through contact with a different infested source.[2]

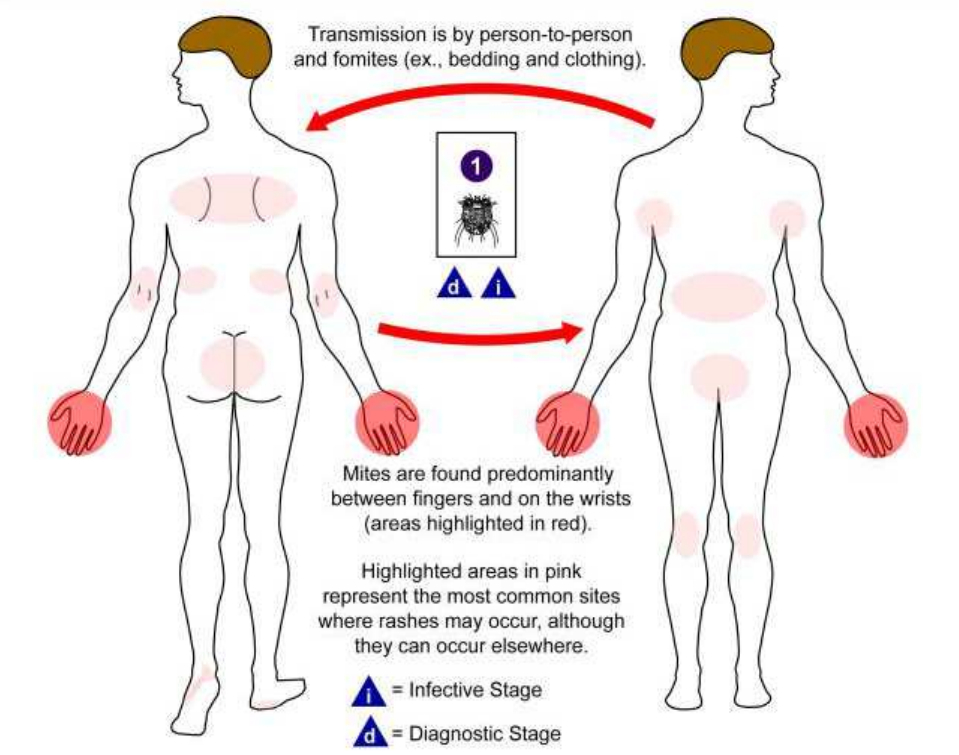


FIGURE 3 : MODES OF DISEASE TRANSMISSION

CLINICAL MANIFESTATIONS:

Scabies has varied clinical manifestations in humans. It mimics many other dermatological conditions such as eczema, impetigo, other pyodermas, fungal infections and contact dermatitis posing diagnostic difficulty[25]. The clinical signs may differ based upon how advanced the infestation is and the sort of inflammation reaction[26]. Secondary infection usually complicates untreated scabies. Pyoderma is a consequence of secondary infection by streptococci and Staphylococcus aureus[27].

Classical scabies patients usually have generalized itching which is aggravated at night[28]. For the itching to manifest, it takes nearly 4-6 weeks and it is most probably due to sensitization.

Classical lesion of scabies:

Burrows are the classical lesion essential for diagnosing scabies. Burrows appear as serpiginous grayish line measuring 5 mm long and it is commonly found where stratum corneum is thin and soft and in places where there are very less or no hair follicles.

Common sites:

1) Sides and interdigital web spaces of fingers and toes
2) Flexor aspect of wrist and elbow
3) Popliteal fossae
4) In females- areola
5) In males- penis, scrotum, gluteal region, umbilicus and belt line[29].
6) In males :

Inflammatory papules or nodules whichare surmounted by burrows are present on male genitalia and are characteristic of Scabies[30]. Male genitalia should be examined thoroughly when a patient is suspected to be suffering from scabies[30]. Genitalia examination helps in clinching the diagnosis.

This special lesion cannot be visualized with naked eye and hence many techniques are available to improve the visualization of mites.

Primary lesions:

- Papules
- Pustules
- Nodules
- Vesicles

Secondary lesions in scabies:

- Excoriation
- Crusting

Special lesions:

1. Burrows
2. Lichen simplex Chronicus

Other lesions:

- Bulla
- Eczematisation

If the infestation is present for longer duration, the secondary lesions are usually more in number and are more obvious than the burrows.The skin rash doesn't usually correlate well with sites of distribution of scabies mite.

Reasons for occurrence of secondary lesions:

These lesions occur as a result of

1) Scratching
2) Secondary infection

Carriers in scabies:

For the infestation with scabies, there is a broad range of responses clinically. Yet few individuals remain without manifesting symptoms and signs of the disease in spite of infestation by the mite. This is akin to the response of human beings to various other insects such as fleas, and mosquitoes, in which also there is a broad spectrum of clinical manifestations. The infested individuals who remain without manifesting symptoms and signs of the disease despite of infestation are referred to as Carriers.

Classification :

Intense pruritus aggravated at night is one of the main manifestation. Skin lesions such as typical comma-like or irregular tunnels which measures from a few millimeters up to a few centimeters are seen[31].

Passages are tunneled by a female scabies mite and it positions itself toward the end of the tunnel[32]. Typical serpentine skin lesions or irregular tunnels of size ranging from few mm to few cm are of diagnostic value[31].

Scabies in young children:

Vesicles, pustules and nodules are unevenly distributed usually over the hands, feet and body folds[17]. In contrast to adults, head, hands and soles of feet may also be involved in addition to other common sites[33].

Scabies burrows, the pathognomonic lesion for scabies occurs often on creases of palms. This follows a pattern of scale reminiscent of the 'wake' left on the surface of water by a moving bird or a ship **(Wake sign)**[34]**.**

The wake sign is specific for scabies and it can be found out by the naked eye and it helps in pointing out the location of the mite and their products.

Scabies in elderly:

The itching may be incorrectly attributed to the condition known as senile pruritus thereby hindering the diagnosis and leading to the misdiagnosis[35].

Nodular scabies:

Cutaneous lesions may present as round, smooth nodules of red/ reddish brown colour and measuring approximately 5-8 mm in diameter. These lesions are usually present in the areas with very thin skin, like genitals/ inguinal folds.

Vesicular scabies:

Vesiculobullous scabies is an uncommon variant. It is seen in elderly people usually. This entity might mimic Bullous pemphigoid both clinically and histologically and even resemble the immunofluorescence findings too. The diagnosis is especially difficult when mites/ fecal pellets cannot be demonstrated[36]. The bulla forms as a consequence of mite's presence in the epidermis of host leading to the specific immunological response. There is activation of T-Helper-2 cells with increase in the level of Interleukin-5 which in turn increases the level of eosinophils and releases proteolyticenzymes near basement lamina. This finally results in blister formation[37,38].

Homeless people:

- Pruritus in a homeless shelter should arouse suspicion of diagnosis of scabies.
- Impetigo and eczematisation are common.

Scabies and HIV:

Scabies is commonly seen in patients infected with HIV. The more severe and unusual forms are commonly seen as the patient becomes immuno suppressed. In advanced HIV disease, crusted scabies can occur.[39-41]

Crusted scabies:

Synonym: Norwegian Scabies

Danielssena and Boeck described a type of scabies in Lepers in Norway and named it as Norwegian scabies[42]. In these patients huge number of mites was present. It has been referred to as 'Scabies Norvegica Boecki" by Von Hebra[43]. The term 'Norwegian' should be probably discarded and replaced by better terms such as Crusted or hyperkeratotic Scabies[44,45]. It is an uncommon, severely disabilitating form and is characterized by infestation of nearly millions of mites. Hyperkeratotic skin crust usually develops.

Pathophysiology:[46,47]

Generally there are only few mites in classical scabies presumably due to scratching which destroys the burrows. This type of scabies occurs in individuals with insufficient immune response, thereby allowing the mites to multiply. This form is associated with considerably higher morbidity compared to classical scabies. Mentally retarded individuals or persons suffering from dementia may succumb to crusted scabies[48]. Down's syndrome is often a commonassociation.[44,49-52] It may be probably because of lack of ability to appreciate pruritus. But the exact reason for association has not been completely understood.

Crusted scabies might develop in immunocompromised individuals, probably due to disease[53-55] or treatment including therapy[55-58] with Infliximab[59] and Toclizumab. In the recent past, there are innumerable reports of crusted scabies occurring in HIV infected patients and it has been reported in

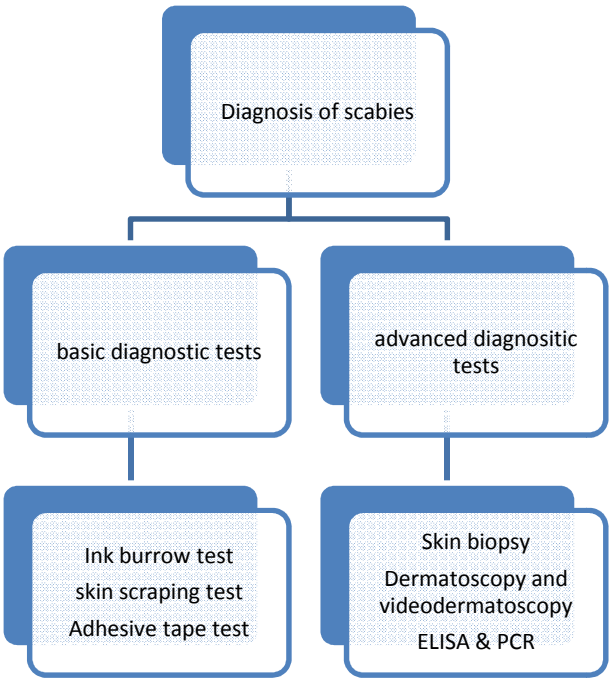
Immune Reconstitution Inflammatory Syndrome[60]. Use of topical steroids[61,62] and calcineurin inhibitors like pimecrolimus[63] may also result in occurrence of crusted scabies.

Clinical Features:[64,65]

Crusted scabies might be localized, involving only scalp, face, digits or soles.Enormous warty crusts may be present on hands and feet, palms and soles that might be irregularly fissured and thickened. Initially erythema and scaling may start over face, neck, scalp and trunk and later on it may become generalised to form erythroderma. Severity of itching may vary. It might be absent, mild or sometimes may be intense. Generalised lymphadenopathy can be present in few cases. On investigations, Eosinophil count and Ig E levels are elevated.

It may be misdiagnosed as hyperkeratotic eczema, psoriasis, Darier disease, contact dermatitis and Langerhans Cell Histiocytosis. Diagnosis can be confirmed by examination of scraping. It is usually teeming with mites and eggs.

DIAGNOSIS OF SCABIES:



BASIC DIAGNOSTIC TOOLS:

Ink burrow test:

Synonym: Burrow Ink test

The underside of a cartridge pen is rubbed on suspected scabies papule and then excess ink is wiped off with an alcohol pad[66]. Ink allows tovisualize the tunnel and it is visualized as dark irregular track. Cartridge pen (with free flowing ink) is inexpensive and simple tool. This method is helpful in anxious individuals and uncooperative patients. This test gives approximately 30% chance of false negative results[67].

Tetracycline test:

An alternative to the burrow ink test is tetracycline test[66]. Solution of topical tetracycline is applied and after application and removal of excess tetracycline solution with alcohol, examination of the burrow is done with

Wood's light[66]. Greenish fluorescence is seen due to the remaining tetracycline within the burrow.

Skin scraping :

Gathering specimen for skin scraping is an invasive method. One drop of mineral oil is added onto the skin lesion, samples of involved skin are gathered using a sterile scalpel. The oil helps in adhering the scraped material to the blade. Skin scraping can be suspended in mineral oil and the material which is collected is placed on the microscope slide and coverslip is placed over it. Scales usually mixes with oil and mites adhere to the oil. Transparent nail polish is used to seal the edges to prevent migration of mites beyond the coverslip[68,69]. The collected material is then examined under the microscope to identify mites, eggs and fecal pellets.

Potassium Hydroxide can also be used instead of mineral oil. Potassium Hydroxide dissolves keratin and help in improving visibility[32]. But it can dissolve fecal pellets.

Inability to discover mites is common and does not preclude the diagnosis of scabies. The microscopic examination of scrapings collected from skin at appropriate sites is usually reckoned as the reference procedure.

Adhesive tape test:

Adhesive tape is used in this test and it is placed over the skin lesion and is then transferred on to the microscopic slide along with tiny separated parts of skin. It is presumed that the Sarcoptes mites are present in the epidermis and its

upper layers may be released by scratching the skin[70]. The benefits of this test include its minimal investment and no requirement for extraordinary training of the staff[68]. The structure of the skin plays a noteworthy part in effective collection of mite by this method of using an adhesive tape.

ADVANCED DIAGNOSTIC TOOLS:

Skin biopsy:

Skin biopsy is an invasive technique for diagnosing scabies. This method makes it conceivable to see the mites and egg in the stratum corneum of the epidermis. However, microscopic analysis reveals nonspecific delayed hypersensitivity reaction. Mites are often absent. This method has low diagnostic sensitivity.Dense infiltrate composedof mononuclear cells with numerous eosinophils is present around papillary and reticular dermal vessels. Onexamination of multiple step sections through the tissue block, pink, pigtail-like structuresthat are connected to the stratum corneum[71]. “Brown nuggets” can be present in cornified layer[72].But skin biopsy shows less diagnostic sensitivity[73].

FIGURE 4 &5 : HISTOPATHOLOGY OF SCABIES

4- PIG TAIL APPEARANCE

5- BROWN NUGGETS IN CORNIFIED LAYER

Dermatoscopy and videodermatoscopy:

Both dermatoscopy and videodermatoscopy are non-invasive methods. With the help of dermatoscope, the skin is observed closely in vivo at a magnification power of 10 times. Videodermatoscope gives even more higher magnification power of 10-1000 times. Both these techniques can be used to screen many sites in a short duration of time. Videodermatoscopy aids in precisely identifying the transparent body of mite and the higher magnification power helps in visualizing other essential diagnostic components such as eggs, scybala[74]. This technique is sensitive, effective and yields quicker results especially in patients with non-specific symptoms. The higher magnification helps in visualizing important diagnostic element and hence the risk of false positive results which may be obtained at lesser magnification power can be obviated[75,76]. The mites which are present at the end of the burrow show a characteristic Jet plane trail appearance of a burrow or Hang glider appearance. These non-invasive techniques are utilized in specialized health care centres as these methods are expensive and hence not widely employed in diagnosing scabies.

ELISA:

The sensitivity and specificity of ELISA may vary. The preparation of extracts of whole mite is conscientious because the mites which are to be cultivated for assays should be taken from the appropriate hosts. The extract which is prepared is used in these tests to detect mites. Another impediment to use ELISA for detection of scabies mite is that no in vitro culture system exists

for this organism[77]. There is a possibility of cross reactivity between house dust mites and Sarcoptes scabiei when extracts from whole mite are utilized for serodiagnosis in humans[78].

PCR :

Polymerase Chain Reaction technique helps in detecting mites in the suspected samples. In patients presenting with atypical scabies, PCR is considered to be trenchant diagnostic method[79]. Following are the disadvantages of ELISA method:

1) Sensitivity of this test is low
2) Expensive
3) Requirement for specialistic laboratory equipment

Due to the above mentioned disadvantages, PCR is considered impractical on a larger scale.

DIFFERENTIAL DIAGNOSIS:

Close mimics:

- Atopic dermatitis
- Dyshidrotic eczema
- Pyoderma
- Contact dermatitis
- Insect bite reaction

Other differential diagnosis:

- Dermatitis herpetiformis
- Psoriasis
- Bullous pemphigoid
- Drug eruption
- Systemic causes of pruritus
- Delusions of parasitosis

COMPLICATIONS:

- Secondary impetiginisation
- Eczematisation

✓ **Psychological:**

- Discomfort from pruritus can result in insomnia
- Extensive psychological reverberation due to embarrassment resulting from conceptualization of disease which is ignominious or which affects underprivileged social classes and
- Stress associated with necessity to inform contacts (family members, sexual partners, inmates and children) as they should also be treated so as to assure a cure[17].

✓ **Work related considerations[17]:**

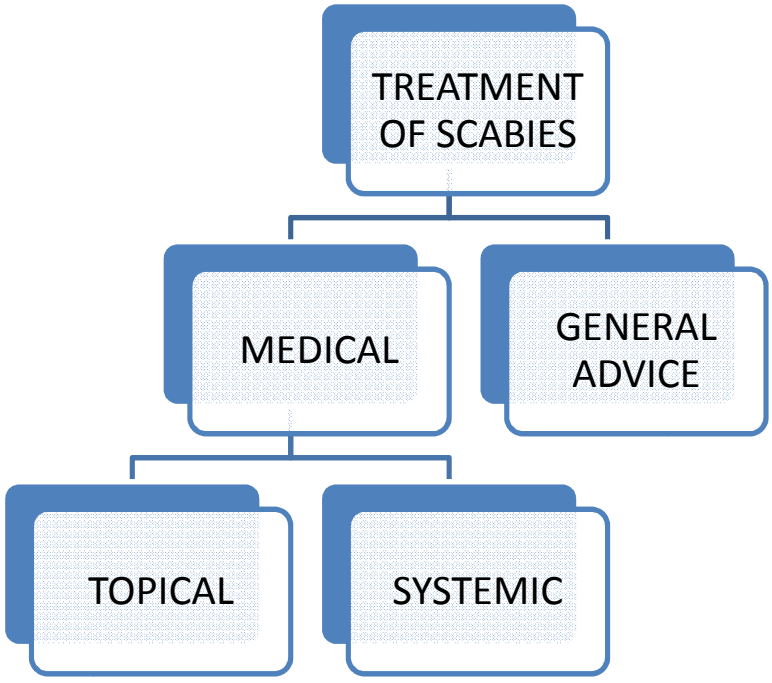
- Absenteeism due to treatment and
- Occupational endangerment to health care personnel and prison employees

- ✓ Keratotic or crusted scabies is highly infectious[17]
- ✓ Toxicity associated with local and systemic treatment

TREATMENT :

Scabies requires triple treatment which includes

1) Treatment of the affected patient.
2) Patient's habiliment and bed linens.
3) Close contact of affected individuals.



Principles of treatment of scabies:

- ✓ Proper diagnosis to be established.
- ✓ An appropriate medication is to be chosen
- ✓ The entire body starting from neck till toes should be treated in adults. In babies, the whole body including head and face must be treated.
- ✓ All the close contacts should be treated.

- ✓ Secondary infection,if present, should be treated.
- ✓ Over treatment should be avoided.
- ✓ Follow up is required at first week and at fourth weeks
- ✓ After completion of treatment, clothing and bedding should be washed.

General advice:

- ➢ All the household members and sexual contacts must be treated at the same time as patients even if they don't have manifestations of the disease
- ➢ Patient is advised to take bath and to thoroughly dry afterwards before applying medicines.
- ➢ The topical drugs must be gently rubbed into the skin. It should be applied all over the body from chin downwards, irrespective of its involvement.
- ➢ The topical medicines should be applied to clean, dry skin by the patients[80].
- ➢ Treatment would be more effective if done in the night before retiring to sleep.
- ➢ Contact with oral cavity or eyes must be avoided.
- ➢ Underclothing and sheets must be changed the next day and it must be washed properly.
- ➢ Nails to be clipped.
- ➢ Itching may persist for few days but doesn't require treatment again.

Topical therapy:

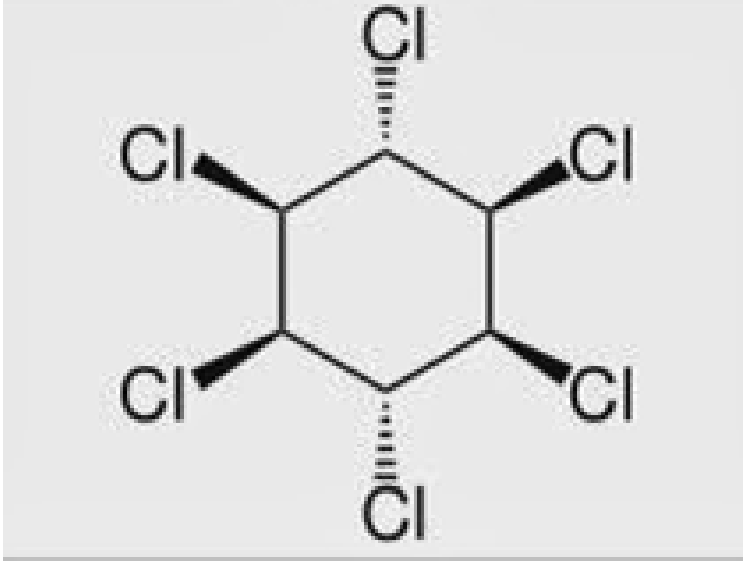
- Permethrin 5% cream
- Lindane (1% Gamma Benzene Hexa Chloride) lotion or cream
- Ivermectin 0.5 % cream
- Benzyl benzoate 10% and 25%
- Malathion 0.5% lotion
- Crotamiton 10% cream
- Monosulfiram 25% lotion
- Esdepallethrine 0.63% aerosol
- Precipitated Sulphur 2-10 % ointment[80]

Oral Drug :Ivermectin[80]

LINDANE: (ORGANOCHLORINE)

Lindane is a Gamma HexaChloroCyclohexane isomer of Cyclohexane family

Figure 6 : Chemical structure of GBHC



Mechanism of Action:

GBHC inhibits neurotransmission, induces respiratory paralysis and muscular paralysis in arthropods and thereby causes death of the mite.

Available Topical Formulations:

1% GBHC lotion

Method of Application:

- Eight to twelve hours overnight application over cool dry skin after shower. The patient is instructed to take bath after 12 hours of application.
- Similar application should be repeated after 10 days-14 days.
- The in vitro efficacy of this drug appears to be equivalent to Benzyl Benzoate with death of the mite occurring after 3 hours of exposure. But it appears to be less effective than Benzyl Benzoate in vivo.
- Few cases of failure has been reported due to mites resistant to Gamma Benzene Hexa Chloride.

Metabolism :

- The drug is distributed throughout the body widely.
- It is metabolized slowly.
- It is stored in the fatty tissues and also in the brain.
- Furthermore, traces of Lindane may be detected in the body even after many months of application.

Pregnancy Category :

This compound belongs to the pregnancy category C

Side Effects:

- Proper application of the drug, rarely causes toxicity from Lindane.
- Nevertheless, recurrent exposure or ingestion affects the central nervous system adversely.
- There are many reports of seizures because of this drug[81-83].
- Innumerous systemic toxic effects have been reported which includes many cases of aplastic anemia and leukemia[84].

Safety:

Higher levels of drug are reported in

- ✓ Infants and children
- ✓ Those with reduced fat levels like premature infants[85].

SYNTHETIC PYRETHRINS:

Permethrin

Esdepellathrin

PERMETHRIN:

Chemical structure:

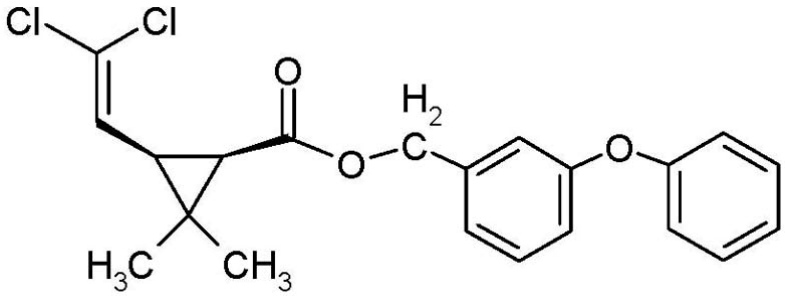


Figure 7 : Chemical Structure of Permethrin

Pyrethrins are originally obtained from species of flowers belonging to the genus Compositae. This is related to Chrysanthemum. Due to the instability of these compounds chemically and comparative ineffectualness, chemists shortly formulated Synthetic pyrethroids like Permethrin. They have broad range of activity against lice, ticks, scabies and numerous other Arthropods.

Permethin is one of the synthetic chemicals belonging to Synthetic pyrethroids. 2 parts of 3-phenoxy benzy (6) and 3 parts of cis and trans-3-(2-2-dichlorovinyl)2,2-dimethylcyclopropanecarboxylate is mixed approximately and it is utilized as Permethrin.

Mechanism of action:

The drug disenables the transport of Sodium across the cell membrane of arthropods. This sodium transport mechanism functions for maintaining polarisation of neuromembranes of arthropods[86]. As a result of the inhibition of Sodium transport across neurons, repolarization is delayed and thereby paralysis of arthropods occur resulting in death of the organism.

Topical formulations available:

- **Permethrin 5% cream :**

  Useful for total body topical therapy for scabies

- **Permethrin 1% cream rinse :**Used for treating head lice.

Method of application :

- ✓ Overnight application all over the body starting from the neck except for face for duration of eight hours.

- ✓ Special attention has to be paid for hands and fingernails as these sites harbor the largest concentration of mites.
- ✓ Intertriginous sites (including interdigital spaces) require cautious application
- ✓ Similar application is recommended to be repeated after a period of one week.
- ✓ Single application of permethrin cream left overnight is necessary to treat all the close contacts of the patient.

By and large, it is consented that patient infested with scabies mite must be treated with two applications which should be left overnight and to be repeated one week later although a study has shown a cure rate of 97.8% with single application.

Pharmacokinetics:

Percutaneous absorption:

Permethrin is absorbed minimally via percutaneous routs. As a result mean systemic absorption after applying Permethrin 5% cream is approximately less than 1-2%

Metabolism:

The drug is metabolized through cleavage of ester and almost the entire absorbed compound is excreted via urine approximately within one week.

Side effects:

- Pruritus
- Mild and transient skin irritation
- Burning sensation
- Rarely hypersensitivity reactions can occur where in the drug usage has to be discontinued.

Pregnancy category:

It belongs to the category B.

Safety:

Due to the minimum systemic absorption, it is safe to be used topically in adults and in infants more than two months of age.

IVERMECTIN:

Ivermectin was first identified in 1970s. It is an important antiparasitic medication. Ivermectin chemically is 22,23-dihydroavermcectin.

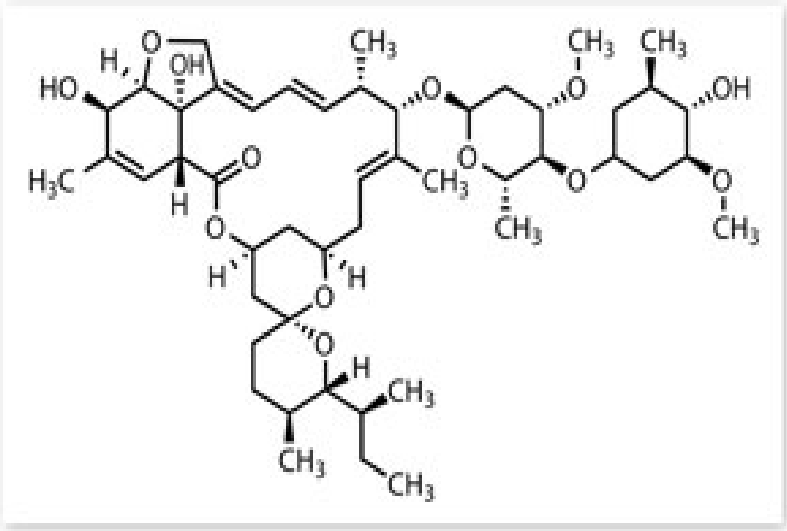


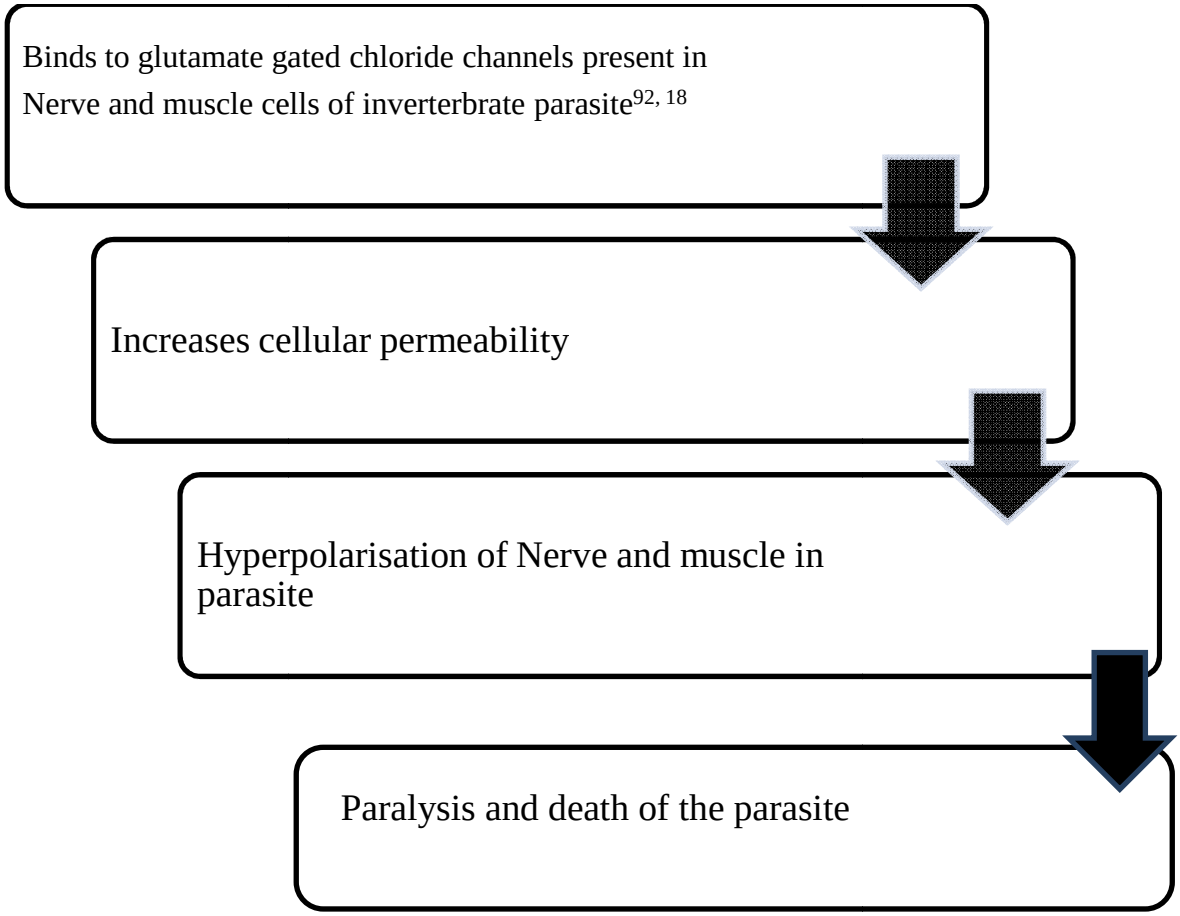
FIGURE 8 : STRUCTURE OF IVERMECTIN

Structurally it is a semisynthetic macrocylic lactone and this chemical is naturally produced by fermentation action of Streptomyces avermitilis in soil[87]. This compound was identified from samples of soil obtained from Japanese Golf course. Initially it was considered only in veterinary treatment, Intensified exploration has lead to the appreciation of its potential use in humans. Extensive research has lead to the approval of drug in 1987 by French Regulatory authorities[88].

The drug is lipophilic in nature. It has broad spectrum of activity and has miticidal and acaricidal activity[89]. The drug has potent antihelmenthic activity and is used for the same property for veterinary and human medicine. It is considered drug of choice for treatment of human onchocerciasis[90]. It is also effectual against lymphatic filariasis[91]. It is also known to have a high degree of toxicity to human ectoparasites including scabies mite.

Mechanism of action:

The drug exerts its action by disrupting neurotransmission in invertebrates which is mediated by Gamma Amino Butyric Acid (GABA) in the peripheral Muscles. The mechanism of action provides this drug a safety profile due to the significant difference between inverterbrates and mammals as far as the distribution of GABA mediated neurons are considered. Gamma Amino Butyric Acid (GABA) mediated neurons are present only in Central Nervous System in mammals but such neurons are present is peripheral muscle in invertebrates. This property accounts for wider safety margin of this drug in mammals as it does not cross the blood brain barrier[92,18].



From the year 1980, Ivermectin is employed effectively and safely via subcutaneous route against scabies mite in pigs, farm foxes, calves, horse dogs and other household pets[93]. In studies which were done previously, the effectuality of oral ivermectin for treatment of endoparasites and ectoparasites has been proven[93]. It has been shown to be effective in scabies, for myiasis in children, onchocerciasis, larva currens and pediculosis in humans. It is now considered the drug of choice for treating and to control human onchocerciasis[93].

After clinical trials which have been done extensively, ivermectin was registered in the year 1986 for its use in humans. Due to its effectuality and its

safety concern, community based treatment of onchocerciasis and ivermectin has been considered as the strategy of choice.

Adverse effects:

- Fever
- Headache
- Pruritus
- Myalgia
- Edema
- Arthralgia

The above said adverse effects are seen in 64% of the patients with first dose whereas it is seen in 50 % of the patients with second dose[93].

These adverse effects are of lesser or moderate intensity and can be treated easily with aspirin and / or antihistamines. It is well tolerated in children more than 5 years of age[93].

Meinking et al[94] have shown that ivermectin at a single oral dosage of 150-200 micrograms per kilogram is an efficient treatment for scabies in otherwise healthy individuals and also in Human Immunodeficiency Virus affected patients.

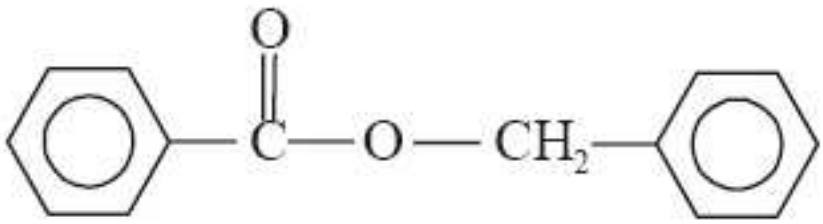
Corbett et al found that the drug was effective even in treatment of crusted scabies by eradicating a nosocomial outbreak in inpatient HIV institution with combination of topical treatment and oral Ivermectin.

It is highly effective antiparasitic animal drug utilized in various forms as injectables, oral and topical formulations. Residues of the drug might reach

the environment through animal waste and manufacturing waste and might potentially have effects on both terrestrial and aquatic organisms[93]. Studies have shown that ivermectin binds avidly to soil and is subjected to photodegradation and biotransformation to lesser active compounds[93].Whereas it has high toxicity to few aquatic organisms but it is not expected to enter aquatic environment[93]. Comparatively lesser toxicity has been demonstrated as regards to bacteria, fungi, earthworms, plants and birds. It has been widely used for treatment of sea lice infestations of farmed Scottish Salmon[93].

BENZYL BENZOATE:

Chemical structure:



Benzyl Benzoate

It is an ester of benzoic acid and benzyl alcohol[96].

Source: derived from Balsam of Peru and tolu[96]

Mechanism of action:

This medication is toxic to the nervous system of the parasite and is also effective against ova.

Formulations available:

- 25% emulsion[17]
- It is diluted to a concentration of 25% and it is very efficacious in vitro, resulting in death of mites within 3 hours[17].
- It can be used alone (10% or 25% lotion) or together with Sulfiram.
- In Young children : dosage should be reduced to 12.5%

Different regimens for application:

- The medicine should be applied for 3 times within 24 hours without intervening bath.
- Twice application 24 hours apart.
- Twice application one week apart.

Toxicity :

Cutaneous side effects:

- Skin irritation – Irritant dermatitis over face and scrotum. If used repeatedly can cause allergic dermatitis.
- Xerosis
- Burning sensation
- Eczema

Systemic Side effects:

Systemic side effects can occur if

- Applied on broken skin
- Children less than 2 years of age have ingested accidentally.

Sulfiram component might have the same antabuse effect as Disulfiram, so alcoholic abstinence should be advised for a minimum duration of 48 hours[96].

Avoid in

- Pregnancy
- Lactation
- Infants
- Young children < 2 years

Benzyl benzoate if applied properly, has good effect but if not applied in a proper manner, it may result in treatment failure.

SULFUR:

It is an oldest scabicidal agent[96,97]. It was not approved by FDA for scabies treatment.

Mechanism of action:

- Antiseptic
- Antiparasitic
- Anti seborrhoeic
- Keratolytic action

Available formulations:

- Used as 6% precipitated sulphur for scabies treatment
- Available as 2-10% creams or ointment

Advantages:

- Topical sulphur can be used safely in
  - pregnancy and
  - neonates, infants less than 2 months of age.
- Inexpensive
- Mass treatment in resource poor countries.
- Can be used when patient cannot tolerate permethrin, lindane and ivermectin.

Side effects:

- Messy
- Malodorous
- Stain clothes and
- Stings the skin.

Contraindication:

Hypersensitivity

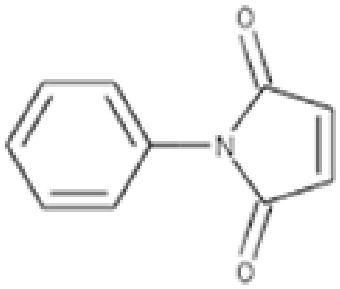
Cautions:

- Avoid contact with eye and mucous membrane
- Discontinue if repeated applications are needed for effectiveness and hence decreased compliance.

CROTAMITON:

Chemical structure:

Crotonyl-N-ethyl-o-toluidine[80]



Available formulations:

10% cream or lotion[80]

Unknown mechanism of action

Method of application:

Twice daily application for 5 consecutive days after bathing.

Success rate: varies ranging from 50-70%

MONOSULFIRAM:

Chemical name:

Tetraethyl thiurammonosulfide

Monosulfiram was first used in 1942 to treat scabies in human by Percival

Method of application:

After bathing, Monosulfiram emulsion is applied all over the body, it must be rubbed well once a day for two to three consecutive days.

Caution:

As this drug is chemically related to antabuse, alcoholic beverages must be avoided during or soon after treatment[80].

In the past, soaps have been used as a preventive measure in infected communities[80].

MALATHION:

It is an organophosphorous insecticide

Its mechanism of action is through irreversible inhibition of Acetylcholinesterase enzyme.

Not recommended nowadays because of its serious adverse effects.

IVERMECTIN:

Oral Ivermectin is given at a dosage of 200 microgram per kilogram. Two doses are given at an interval of 2 weeks.

Special situations:

Neonates and pregnant women should be treated for scabies only if benefit outweighs the risk and if diagnosis is confirmed.

TREATMENT FAILURE

1) Improper application
2) Inadequate application
3) Reinfestation
4) Resistance

NEWER DRUGS:

The search for finding out ideal scabicide is still in process. Due to the emerging resistance to the current drugs, the role of newer drugs in treating scabies becomes more important.

Essential oil of the tea tree:

- It is an Australian traditional medicine which is used for treating bruises, skin infections and insect bites.
- It is a membrane- active biocide which is extracted from the tree *Melaleuca alternifolia.*
- Oxygenated terpenoids are the primary active components.

OTHER NATURAL AGENTS:

- 20% lippia oil
- Camphor oil
- Neem and turmetic paste
- Coconut and jojoba oil mixture

PREVENTION OF SCABIES:

- All the household members and sexual contacts should be treated at the same time even if they are asymptomatic.
- Proper advice to the patient and household members.
- Persons in close contact with crusted scabies patient must be treated as it is very easily transmissible.
- Early detection of scabies is essential to prevent further transmission to other individuals and to prevent other complications like secondary bacterial infections.

AIMS AND OBJECTIVES

AIM OF THE STUDY

1. To compare the efficacy of Topical Ivermectin and other scabicidal agents

2. To assess the improvement in severity of pruritus & Severity of lesions with treatment.

MATERIALS AND METHODS

MATERIALS AND METHODS

4.1 Type of study : Prospective & Comparative study

4.2 Study approval : Prior to commencement of this study - Thesis & Ethical Committee of Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai had approved the thesis protocol.

4.3 Place of study : Rajiv Gandhi Government General Hospital

4.4 Period of study : Duration starting from October 2015 to August 2016

4.5 Sample size : 90 cases

4.6 Selection of patients:

a) Inclusion criteria-

1. Patients of above 5 years and below 60 years of age.
2. Patients of both sexes.
3. Patients willing for topical therapy.
4. Primary case of scabies.
5. Patients willing for follow-up in the second and sixth week or if any

b) Exclusion criteria:

1. Children below 5 years, elderly patients more than 60 years
2. Pregnant and lactating women.
3. Patients who were not willing to come for follow-up.
4. Any serious systemic illness.
5. Prior use of topical or systemic scabicide in last 4 weeks

6.Patients on radiotherapy, steroids or other immunosuppressive drugs for any systemic or cutaneous indication

7. Hypersensitivity to permethrin or ivermectin.

4.7 Study procedure:

Around 90 patients with Scabies were selected from the patients attending out-patient clinic in Department of Dermatology, Madras Medical College. All patients were explained about the disease, benefits and possible side effects of treatment. Informed written consent was obtained from all patients before initiation of treatment. Detailed case history of each patient with reference to the duration of itching, worsening during night, similar illness in family members or inmates was noted.

Clinical features like classical site of involvement, morphology of lesions, and other associated systemic and cutaneous disorders were noted. Thorough clinical examination of classical sites with magnifyinglens, burrow ink test or examination after applying mineral oil application was done.

The diagnosis was made after detailed history and clinical examination In doubtful cases, demonstration of scabies mite, eggs or faeces was done by scraping from burrows or finger nails.

The patients were randomly allotted to any one of the following three treatment groups after calculating their Severity of Pruritus and Severity of lesions.

Group A comprised patients who will be given 1% GBHC lotion. .

Group B comprised patients who will be given 5% Permethrin cream

Group C comprised patients who will be given 0.5% Ivermectin cream.

4.8 Follow Up Assesment :

SCREENING PROCEDURES or VISITS: Patients were advised to come for review after 1 week for second application and in third week and in sixth week.

ASSESSMENT OF PARAMETERS[98]:

Parameters used to compare the efficacy of the groups by was based on improvement in

1) severity of pruritus
2) severity of the disease

1) *Severity of pruritus* was evaluated by Visual Analogues Scale (VAS). VAS was considered as a 10 cm line, in which point 0 (zero) refers to existence of no pruritus and point 10 refers to the most severe pruritus. According to this scale, we scored pruritus of the patients

   Point 1 to 3 - Mild pruritus

   Point 4 to 6 - Moderate pruritus

   Point 7 to 10 - Severe pruritus

2) *Severity of the disease* is measured according to the number of lesions present. It can be graded as

   Mild - less than or equal to 10 lesions

   Moderate - 11-49 lesions

   Severe - more than or equal to 50 lesions or Crusted

Severity scores of 1, 2, 3 and 4 were assigned to scabies cases recorded as mild, moderate, severe and crusted, respectively.

Patients were then divided into three categories based on these parameters into Good Responders, Moderate Responders &Poor Responders.

Good Responders :

Complete resolution of lesions

Moderate Responders :

Patients post treatment, >50% improvement in pruritus and severity of lesions score

Poor Responders :

Patients post treatment improvement less than or equal to 50%

Cases were followed up for a period of two more months to look for relapse in the patients. In patients who had relapsed, demonstration of mites was done to confirm the diagnosis.

4.9 Variables studied:

Dependent variable: Severity of pruritus and severity of lesions

Independent variables:

i) Age

ii) Sex

iii) occupation

iv) Socio economic status

v) Symptoms

vi) Secondary infection

vii) Associated skin diseases

viii) Presence of similar complaints in inmates and family members (Inmates are those who are living and sharing bed with the patient – for example those living in hostel)

ix) Dermatological Examination

x) Blood Investigations

Patient were followed up for two more months to look for signs of relapse. In cases of relapse, scraping was done to demonstrate mites.

4.10 Ethical consideration

All the patients/ legal guardians were given an explanation of the study and about the investigative and treatmental procedures with their merits and demerits, expected results, and possible complications. If the patient or the guardian for children had agreed, then the case had been selected for this study. The study did not involve any additional investigation or any significant risk. It did not cause economic burden to the patients. The study was approved by the institutional review board prior to commencement of data collection. Informed consent was taken from each patient/guardian. Data was collected by approved data collection form.

4.11 Data collection

Data were collected by pre-tested structured questionnaire. Data were collected from all the respondents by direct interview after getting informed written consent from them or from their legal guardian.

4.12 Data analysis

Data analysis was done both manually and by using computer. Calculated data were arranged in systemic manner, presented in various table and figures and statistical analysis was made to evaluate the objectives of this study with the help of Statistical Package for Social Science (SPSS).

OBSERVATIONS AND RESULTS

OBSERVATION AND RESULTS

This prospective and comparative study was carried out to determine the favourable treatment modality for patients suffering from scabies. Ninety patients with Scabies were selected purposively from Department of Dermatology of Madras Medical College and Rajiv Gandhi Government General Hospital during the period of 1 October 2015 to 31 August 2016. All cases were evaluated clinically and essential investigations necessary for diagnosis were carried out. Severity of pruritus and Severity of lesions score of patients at baseline were calculated and recorded. Patients were then randomly divided into three groups and started on treatment with Topical ivermectin, topical permethrin and topical GBHC. Patients response to treatment was followed up with Severity of pruritus score and severity of lesions score at second, third and sixth week of treatment. Based on the assessment of these scores, the response to treatment was categorised into Good, Moderate and Poor. All data were collected and analysed and results derived.

TABLE 1- DISTRIBUTION OF STUDY POPULATION ACCORDING TO AGE AND SEX

Age / Sex	Male n (%)	Female n (%)	Totaln(%)
6-15	12 (13.3%)	10(11.1%)	22 (24.4%)
16-25	13(14.4%)	10(11.1%)	23 (25.5%)
26-35	9(10%)	9(10%)	18 (20%)
36-45	7(7.77%)	9(7.77%)	16 (17.7%)
46-55	5(5.55%)	6(6.66%)	11 (12.2%)

It was observed from our study that nearly 45 out of patients belonged to the younger age group ranging from 6-25. Mean age group of the study population is 27.66 years.

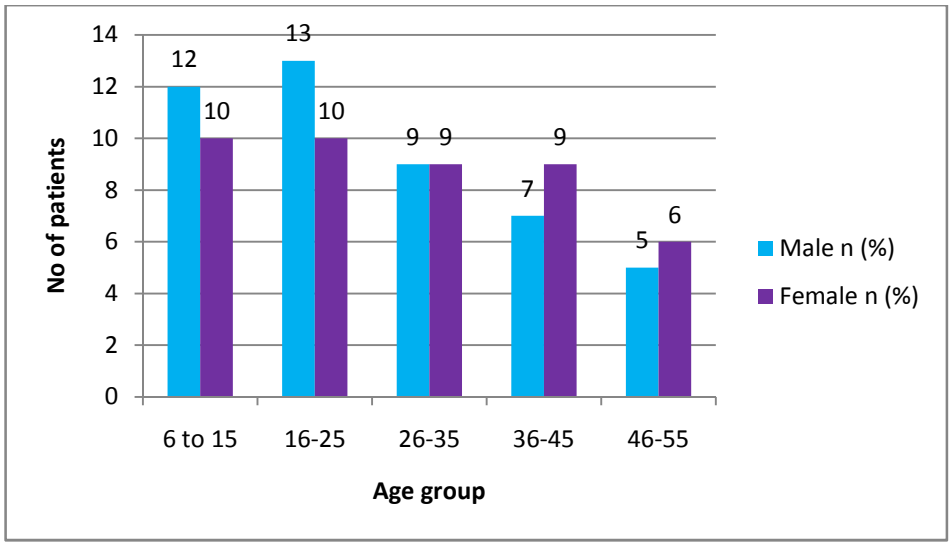


CHART 1- DISTRIBUTION OF STUDY POPULATION ACCORDING TO AGE

TABLE 2 : DISTRIBUTION OF STUDY POPULATION

ACCORDING TO SEX

Age / Sex	NO OF PATIENTS
MALE	38 (42.2%)
FEMALE	34 (37.8%)
CHILDREN	18 (20%)
TOTAL	90

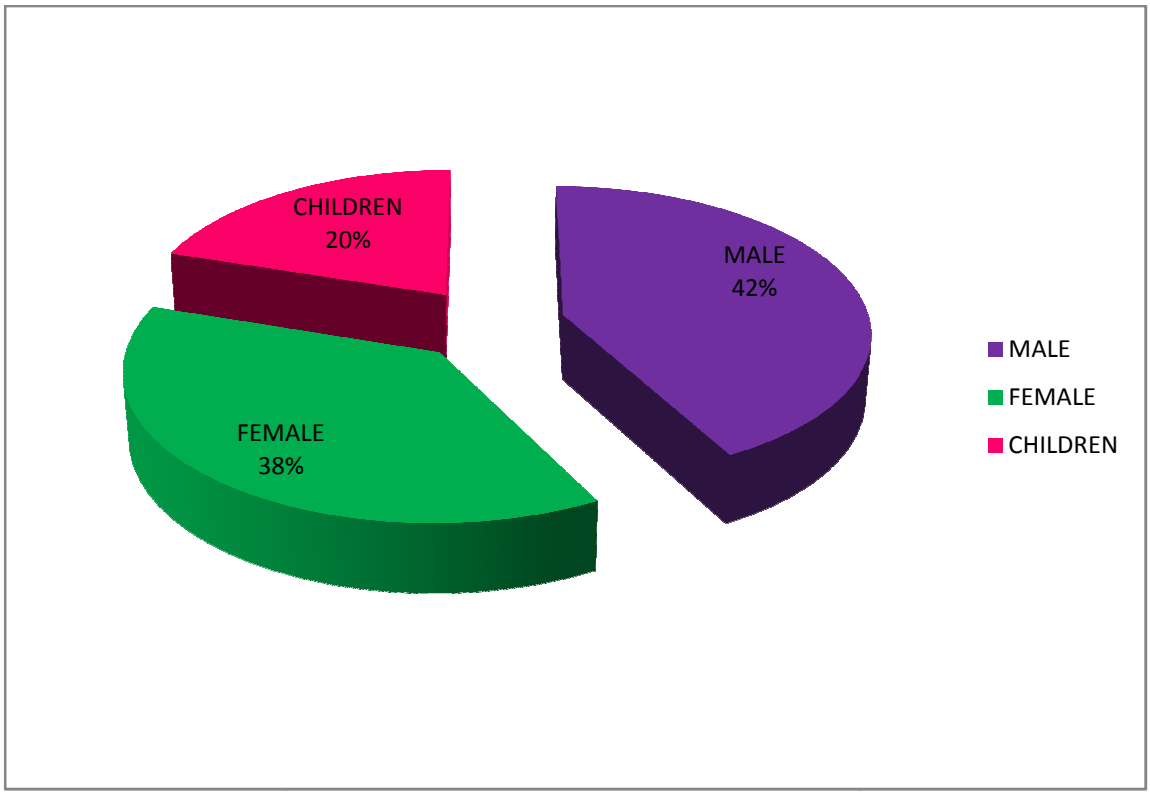


CHART 2 : DISTRIBUTION OF STUDY POPULATION

ACCORDING TO SEX

TABLE- 3 DISTRIBUTION OF CHILDREN AMONG STUDY POPULATION:

	Male n (%)	Female n (%)
GROUP A (GBHC)	3	3
GROUP B (PERMETHRIN)	4	2
GROUP C (IVERMECTIN)	3	3
TOTAL	10	8

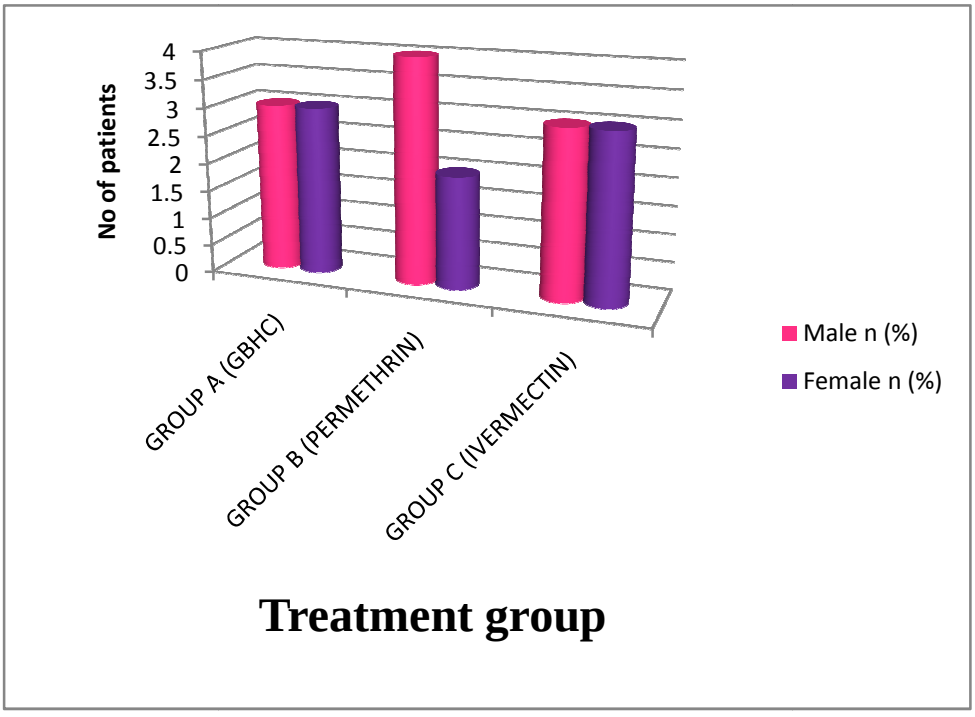


CHART- 3 DISTRIBUTION OF CHILDREN AMONG STUDY POPULATION:

TABLE 4- DISTRIBUTION OF STUDY POPULATION ACCORDING TO SEX

TREATMENT GROUP	Male n(%)	Female n(%)	Total N
A (GBHC)	16 (17.8%)	14(15.6%)	30
B (PERMETHRIN)	15(16.7%)	15(16.7%)	30
C (IVERMECTIN)	16(17.8%)	14(15.6%)	30
TOTAL	47	43	90

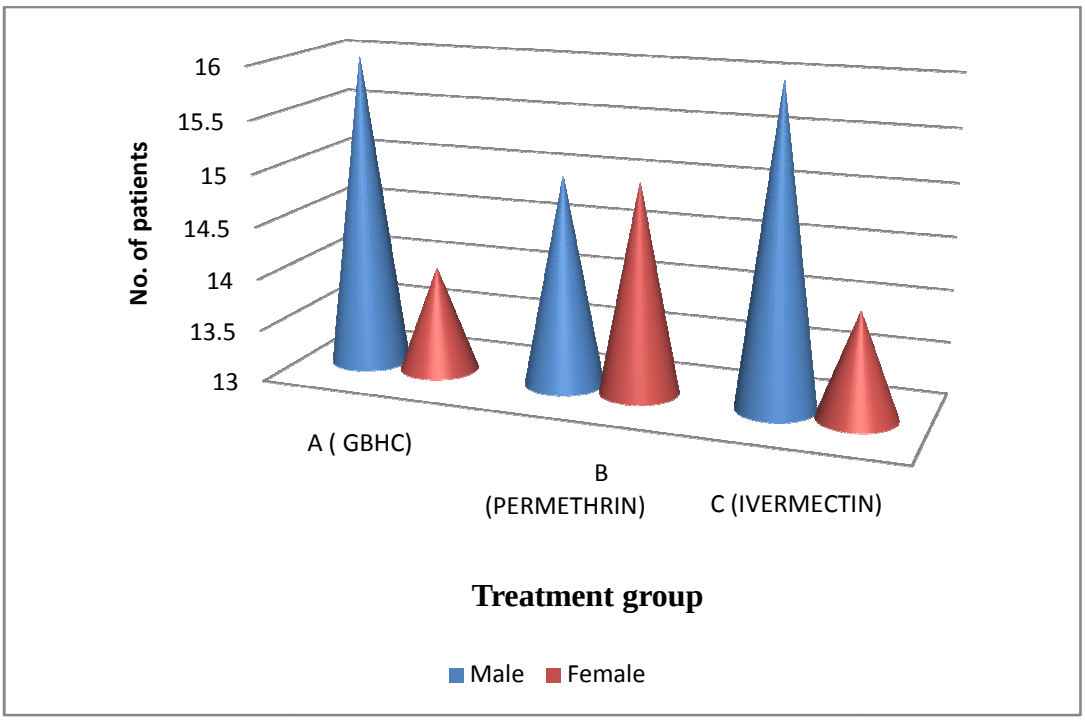


CHART 4- DISTRIBUTION OF STUDY POPULATION ACCORDING TO SEX

TABLE 5- DISTRIBUTION OF STUDY POPULATION ACCORDING TO URBAN/RURAL RESIDENCE

TREATMENT GROUP	URBAN n (%)	RURAL n (%)
A (GBHC)	20 (22.2%)	10 (11.1%)
B (PERMETHRIN)	25(27.8%)	5(5.6%)
C (IVERMECTIN)	17(18.9%)	13(14.4%)

Scabies was most common in urban population in our study group . Out of the 90 patients studied, nearly 62 (68.9%) patients belonged to urban area whereas 28 (30.1%) belonged to rural area.

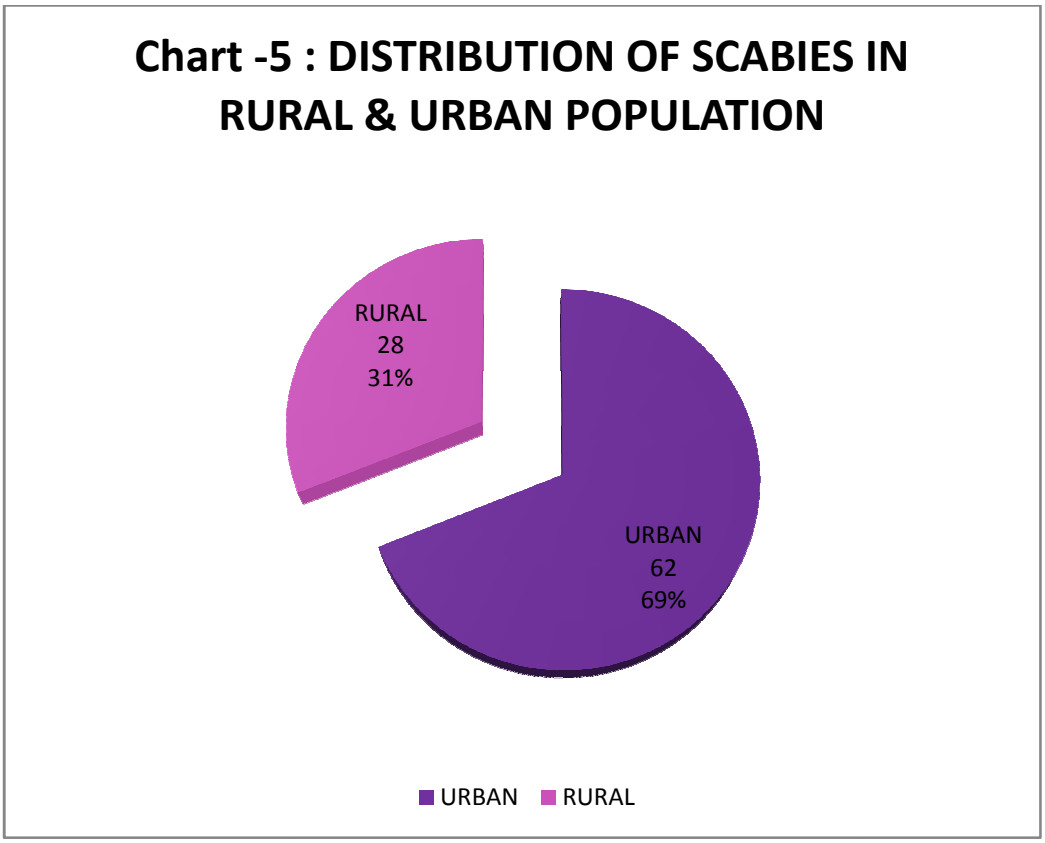


TABLE 6 : DISTRIBUTION OF STUDY POPULATION IN RURAL AREA

Age / Sex	NO OF PATIENTS n (%)
MALE	6
FEMALE	13
CHILDREN	9
TOTAL	28

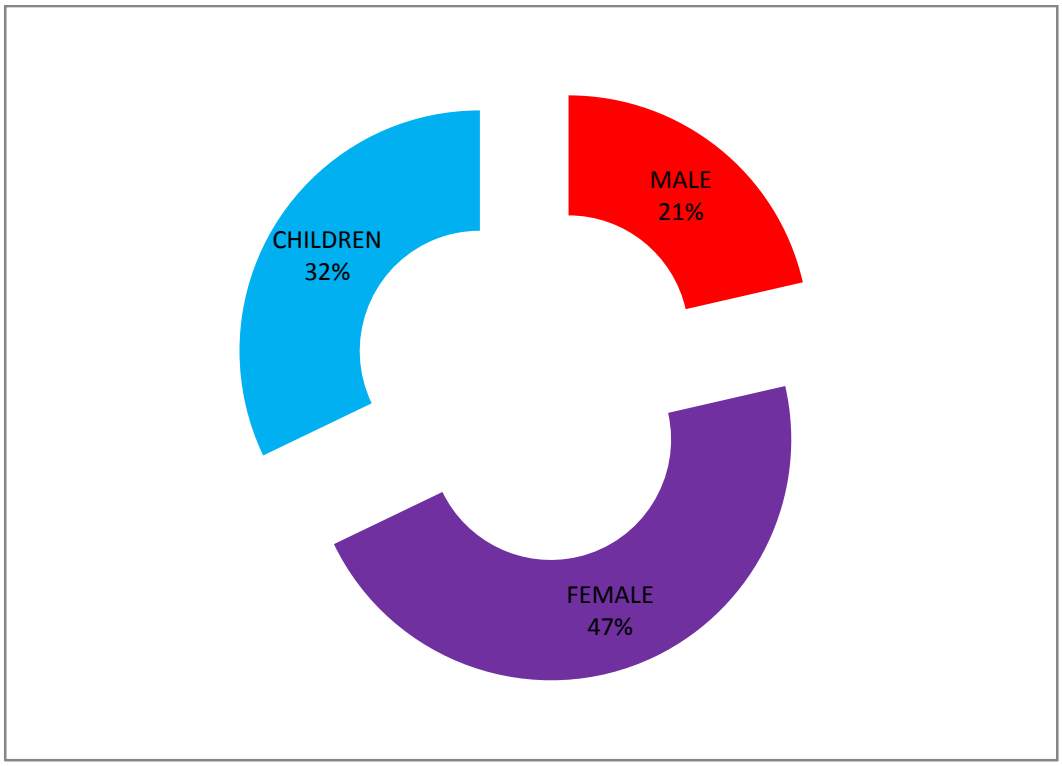


CHART 6 :DISTRIBUTION OF STUDY POPULATION IN RURAL AREA

TABLE 7 : DISTRIBUTION OF STUDY POPULATION IN URBAN AREA

Age / Sex	NO OF PATIENTS n (%)
MALE	29
FEMALE	22
CHILDREN	11
TOTAL	62

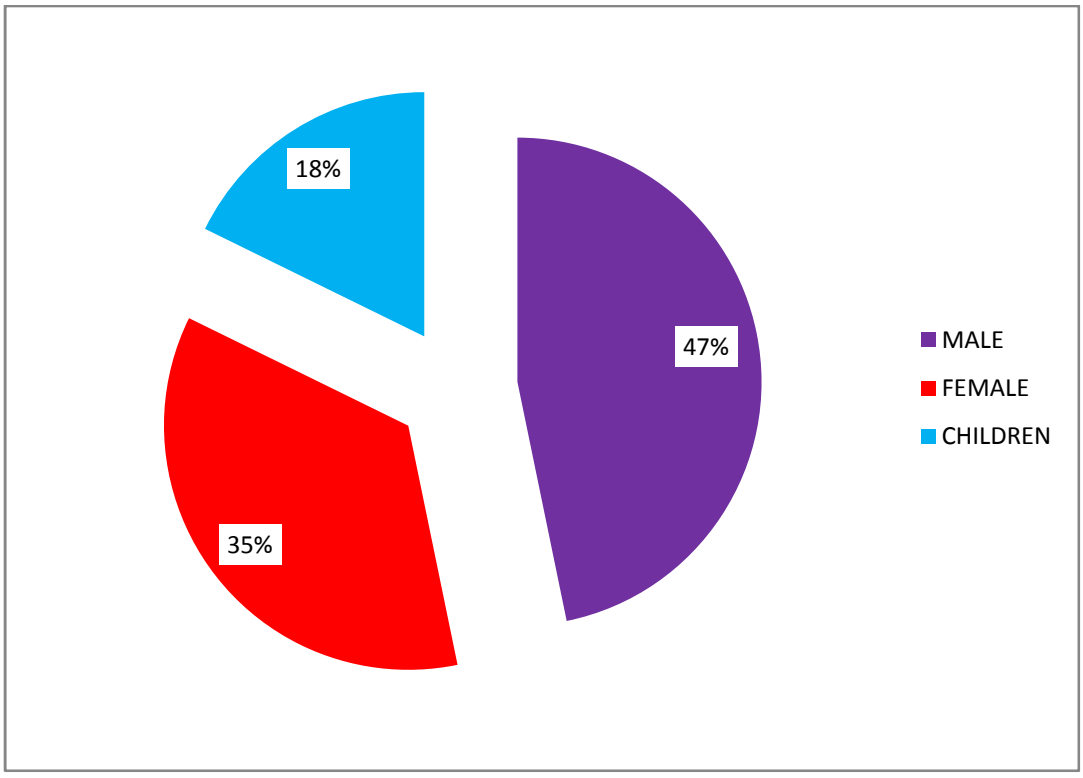


CHART 7 : DISTRIBUTION OF STUDY POPULATION IN URBAN AREA

TABLE 8- DISTRIBUTION OF STUDY POPULATION ACCORDING TO SOCIOECONOMIC STATUS

SOCIOECONOMIC STATUS	NO OF PATIENTS
CLASS 2	1(1%)
CLASS 3	18(20%)
CLASS 4	40(45%)
CLASS 5	31 (34%)

Scabies was most common in lower socioeconomic group according to modified kuppusamy scale. In lower socioeconomic group it is more common probably due to overcrowding, poor sanitation and unhygienic environment.

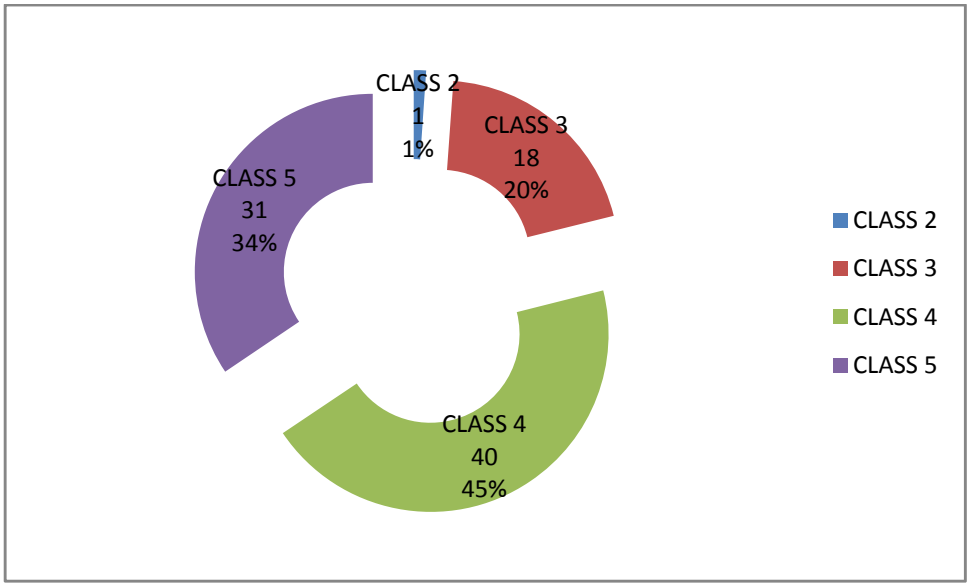


CHART 8- DISTRIBUTION OF STUDY POPULATION ACCORDING TO SOCIOECONOMIC STATUS

TABLE 9- DISTRIBUTION OF STUDY POPULATION ACCORDING TO WHETHER INMATES- AFFECTED OR NOT

INMATES	NO OF PATIENTS
AFFECTED	69(76.7%)
NOT AFFECTED	21(23.3%)

In our study group, 69 patients, i.e. 76.7% gave similar history of itching and skin lesions in close contacts and family members . 20 children, 21 female and 28 male patients had history of scabies in their close contacts.

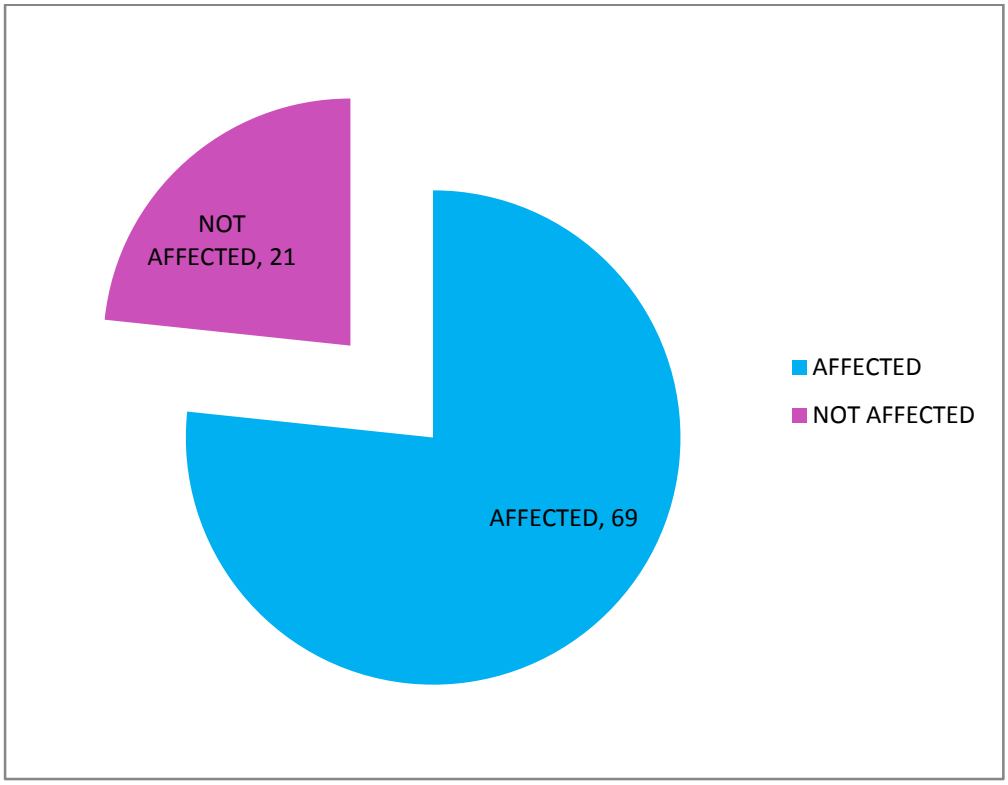


CHART 9- DISTRIBUTION OF STUDY POPULATION ACCORDING TO WHETHER INMATES- AFFECTED OR NOT

TABLE 10- DISTRIBUTION OF STUDY POPULATION ACCORDING TO DURATION OF DISEASE

DURATION OF SYMPTOMS (IN DAYS)	NO OF PATIENTS n (%)
0-7	6 (6.7%)
8-14	37 (41.1%)
>15	47(52.2%)

In our study, majority of patients, nearly 47 patients (52.2%) presented with more than 15 days duration of symptoms.

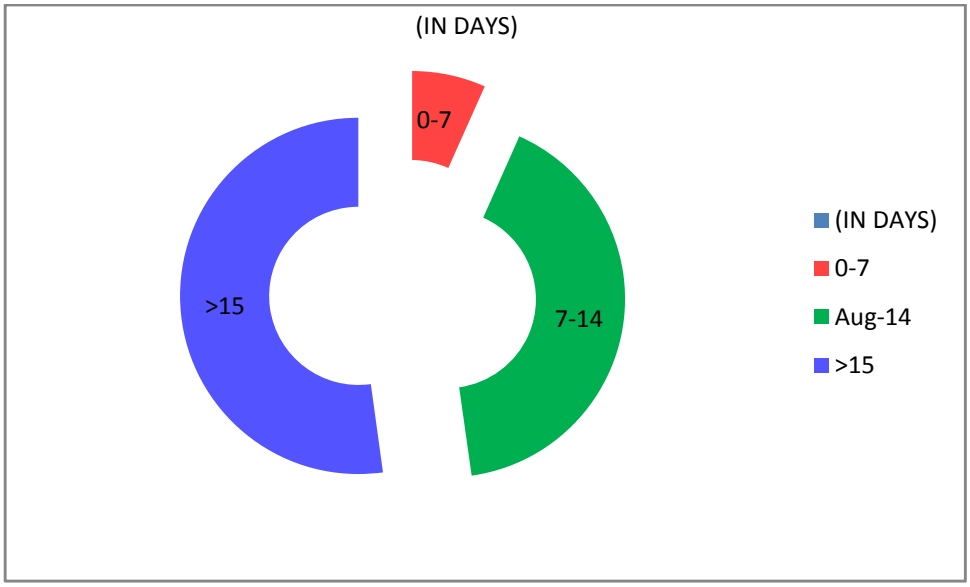


CHART 10- DISTRIBUTION OF STUDY POPULATION ACCORDING TO DURATION OF DISEASE

TABLE 11- DISTRIBUTION OF STUDY POPULATION ACCORDING TO BLOOD GROUP

BLOOD GROUP	NO OF PATIENTS n (%)
A +ve	24
A –ve	2
B+ve	25
B –ve	2
O+ve	34
AB +ve	2
AB -ve	1

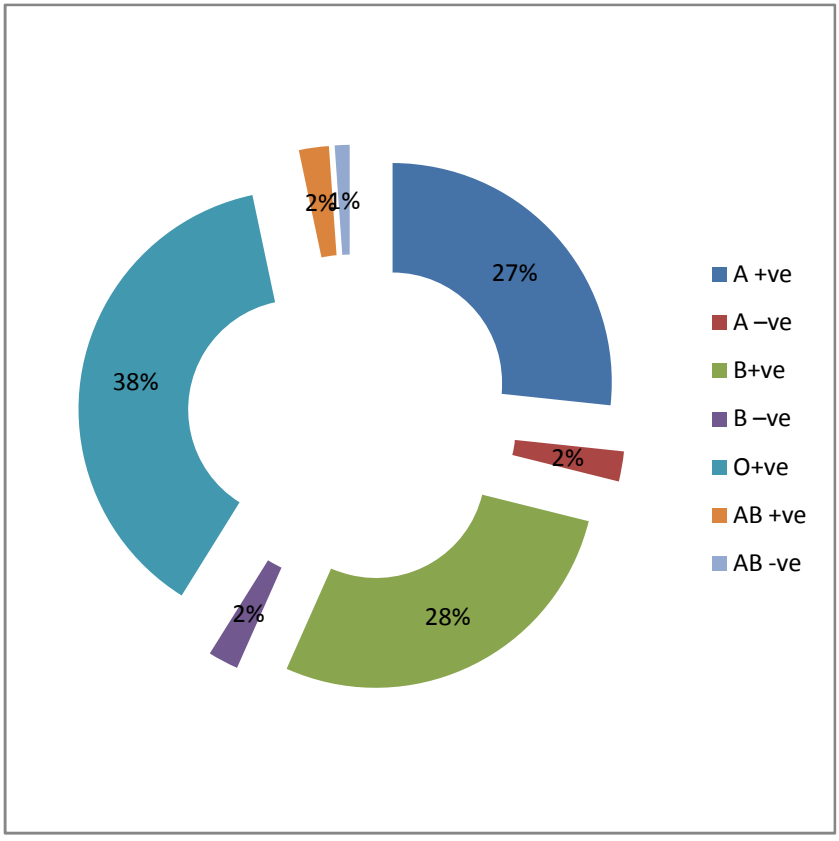


CHART 11- DISTRIBUTION OF STUDY POPULATION ACCORDING TO BLOOD GROUP

Scabies was most common among O positive individuals in our study group. Nearly 34 (38%) patients out of 90 patients belonged to O positive blood group.

TABLE 12 :PREVALENCE OF SECONDARY INFECTION IN STUDY POPULATION

SECONDARY SKIN INFECTION	NO OF PATIENTS n (%)
PRESENT	17 (18.8%)
ABSENT	73(81.11%)

In the study population, out of 90 patients, nearly 17 patients, that is 18.8 % of patients had associated secondary infections.

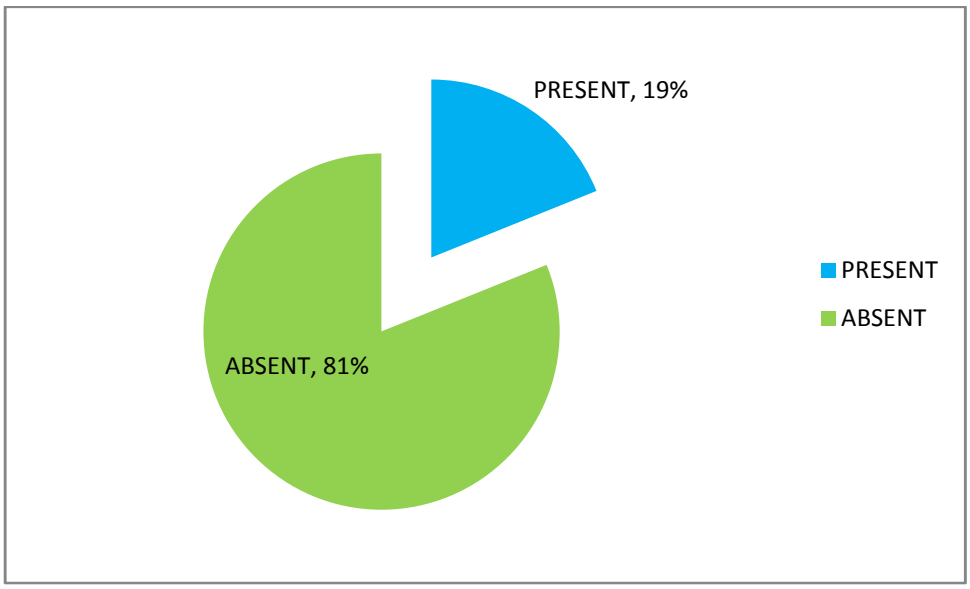


CHART 12 : PREVALENCE OF SECONDARY INFECTION IN STUDY POPULATION

TABLE 13 :PREVALENCE OF SECONDARY INFECTION IN STUDY POPULATION ACCORDING TO AGE AND SEX

Age / Sex	NO OF PATIENTS n (%)
MALE	5
FEMALE	8
CHILDREN	4
TOTAL	17

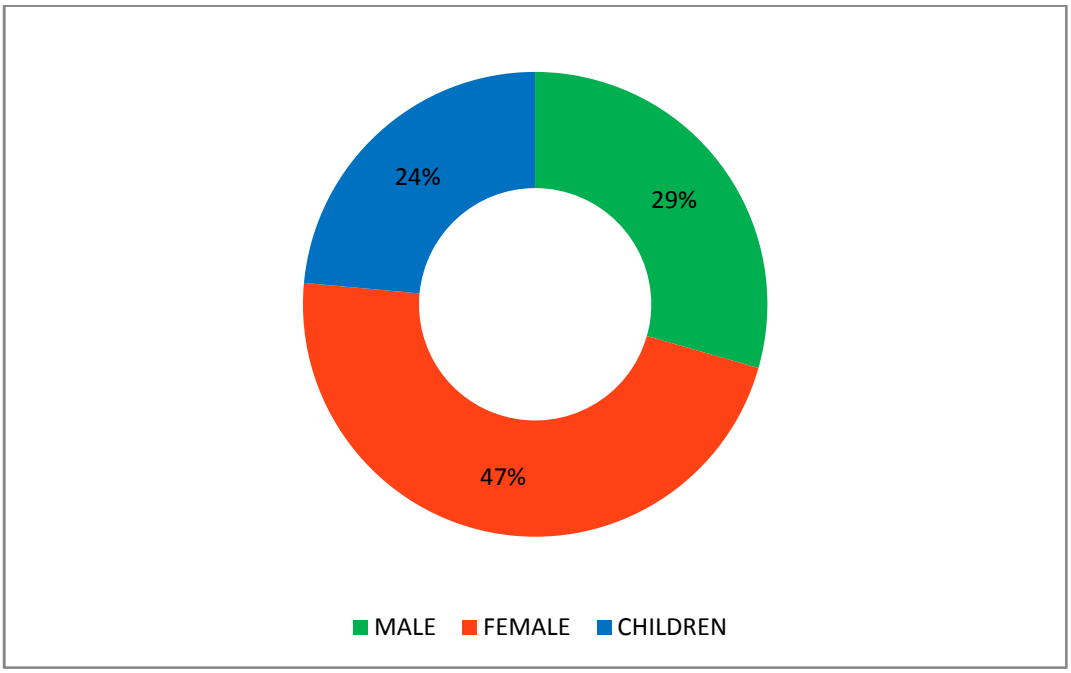


CHART 13 :PREVALENCE OF SECONDARY INFECTION IN STUDY POPULATION ACCORDING TO AGE AND SEX

TABLE 14 :PREVALENCE OF ASSOCIATED SKIN DISEASE IN STUDY POPULATION

ASSOCIATED SKIN DISEASES	NO OF PATIENTS n (%)
DERMATOPHYTE INFECTION	9 (8.88%)
SECONDARY BACTERIAL INFECTION	17 (18.8%)
NIL	66(72.22%)

Out of the 90 patients studied, 9 (8.88%) patients had associated dermatophyte infection and 17 (18.8%) patients had associated secondary infection and others had no associated skin manifestations.

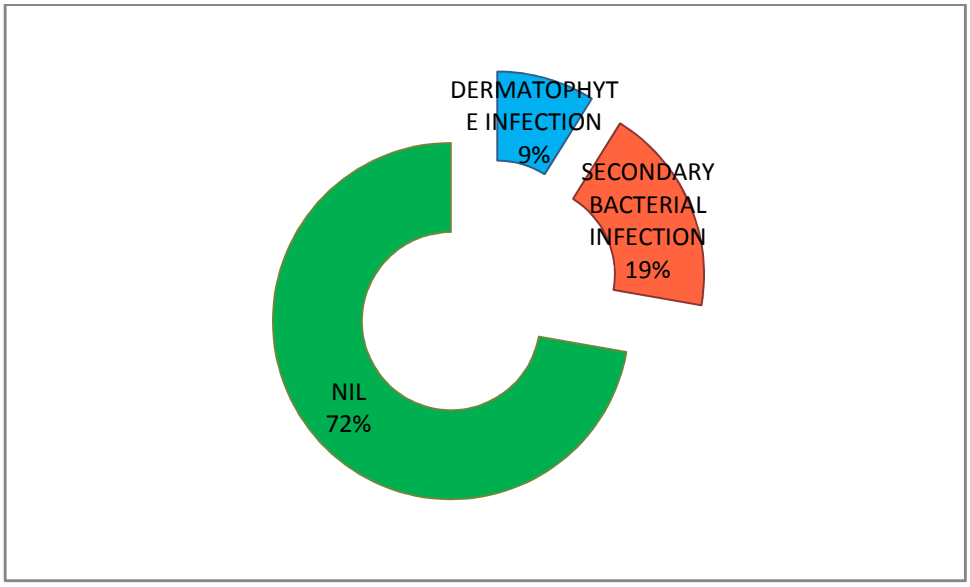


CHART 14 :PREVALENCE OF ASSOCIATED SKIN DISEASE IN STUDY POPULATION

TABLE 15 : PREVALENCE OF ASSOCIATED SKIN DISEASE IN STUDY POPULATION ACCORDING TO AGE AND SEX

Age / Sex	NO OF PATIENTS n (%)
MALE	7
FEMALE	13
CHILDREN	6
TOTAL	26

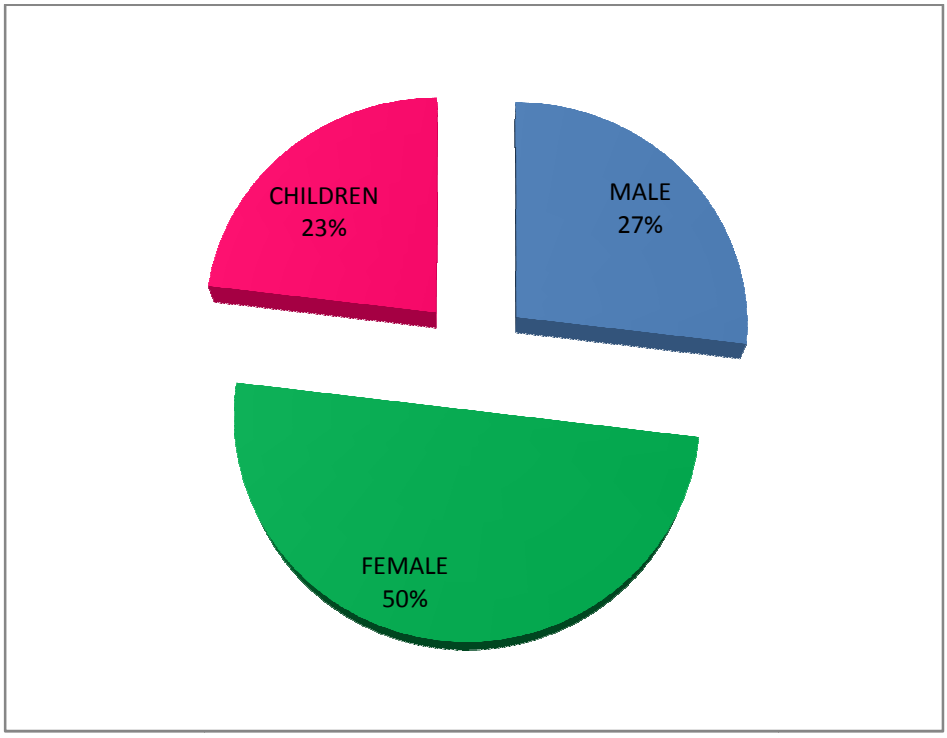


CHART 15 : PREVALENCE OF ASSOCIATED SKIN DISEASE IN STUDY POPULATION ACCORDING TO AGE AND SEX

TABLE16 : PREVALENCE OF HIV INFECTION IN STUDY POPULATION

HIV	NO OF PATIENTS n (%)
POSITIVE	7 (7.8%)
NEGATIVE	83(92.2%)

Seven patients were found to be HIV positive in our study group. Among the HIV positive patients, six were males and one female patient was found to be positive.

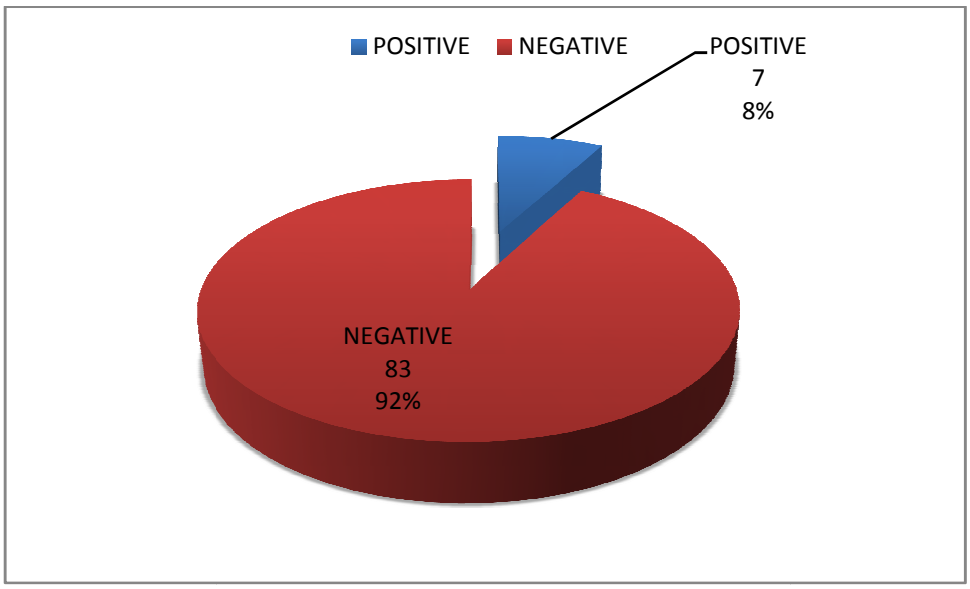


CHART 16 : PREVALENCE OF HIV INFECTION IN STUDY POPULATION

COMPARISON OF TREATMENT GROUP:

- Overall significance of treatment groups was assessed by using Friedman test to find out the p value and chi square value.
- Post hoc analysis was done with Wilcoxon Signed Rank tests to determine which group had significant improvement.

AT PRESENTATION:

There was no statistical significant difference in the severity of pruritus and severity of lesion score in all the three groups .

i) **SEVERITY SCORE FOR PRURITUS:**

Using Friedman test, the severity score for pruritus of the three groups were compared and the analysis revealed Chi square value of 8.083 at degree of freedom of 2 and p value of .018 which was insignificant.

Z	Drug A	Drug B	Drug C
Drug A	-NA-	-1.225 p(.209)	-1.852 p(.064)
Drug B	-1.225 p(.209)	-NA-	-.729 p(.429)
Drug C	-1.852 p(.064)	-.729 p(.429)	-NA-

TABLE 17 : COMPARISON OF PRURITUS SCORE AT BASELINE

	P value
GBHC Vs Permethrin	p <0.05
GBHC vs Ivermectin	p <0.05
Permethrin Vs Ivermectin	p <0.05
Chi square value : 8.083 degree of freedom: 2	

The above table shows comparison of severity scores using Wilcoxon signed rank test and the p values obtained for severity score for pruritus is insignificant.

ii) **SEVERITY SCORE FOR LESIONS:**

The severity score for lesions of 3 groups at the time of presentation was compared using Friedman test and it revealed Chi square value of 2.526 at degree of freedom 2 and there was no significant difference in the severity scores (0.283).

Z	**Drug A**	**Drug B**	**Drug C**
Drug A	-NA-	-.729 (p:0.466)	-2.189 (p:0.029)
Drug B	-.729 (p:0.466)	-NA-	-0.809 (p:0.418)
Drug C	-2.189 (p:0.029)	-0.809 (p:0.418)	-NA-

TABLE 18 : COMPARISON OF LESIONS SCOREAT BASELINE

	P value
GBHC VsPermethrin	p <0.05
GBHC vsIvermectin	p <0.05
PermethrinVsIvermectin	p <0.05
Chi square value : 2.526 degree of freedom: 2	

From the above table we can see that p values obtained for severity score for lesions in each group were not statistically significant at the time of presentation

AT THIRD WEEK:

At the time of first follow up after completion of two applications of scabicidal agents, improvement in terms of severity of pruritus and severity of lesions in each group were again reassessed to find out the effects of the drug.

i) **SEVERITY SCORE FOR PRURITUS:**

The pruritus severity score of the three groups were compared using Friedman test and the analysis revealed **Chi square value of 51.185 at degree of freedom of 2.p value being less than 0.001** revealed significant difference in pruritus severity scores in the three groups.

Z	**Drug A**	**Drug B**	**Drug C**
Drug A	-NA-	-1.808(p: .071)	-4.829 **(p <0.001)**
Drug B	-1.808(p: .071)	-NA-	-4.821 **(p <0.001)**
Drug C	-4.829 **(p <0.001)**	-4.829 **(p <0.001)**	-NA-

TABLE 19 : COMPARISON OF PRURITUS SCORE AT THIRD WEEK

	P value
GBHC VsPermethrin	p <0.05
GBHC vsIvermectin	**(p <0.001)**
PermethrinVsIvermectin	**(p <0.001)**
Chi square value : 51.185 degree of freedom: 2	

To find out which group had caused significant improvement in severity of pruritus - Post hoc analysis with Wilcoxon signed-rank tests was conducted with a Bonferroni correction applied, resulting in a **significance level set at p < 0.017.** Median (IQR) perceived effect levels for drug A, drug B and drug C

trial were 5,4 and 1 respectively. There were no significant differences between drug B and Drug A lesions score trials (Z = -1.808, p = 0.071). However, there was a statistically significant reduction in pruritus severity in the drug C vs drug A trial (Z = -4.829, p = <0.001) and Drug C vs drug B trial (Z= -4.821, p= <0.001).

ii)**SEVERITY SCORE FOR LESIONS:**

The lesions severity score of the three groups were compared using Friedman test .Statistical analysis revealed **Chi square value of 43.948 at degree of freedom of 2. p value being less than 0.001** revealed significant difference in lesions severity scores in the three groups.

Z	**Drug A**	**Drug B**	**Drug C**
Drug A	-NA-	-1.893 (p: 0.058)	-4.790 **(p: <0.001)**
Drug B	-1.893 (p: 0.058)	-NA-	-4.551 **(p: <0.001)**
Drug C	-4.790 **(p: <0.001)**	-4.551 **(p: <0.001)**	-NA-

TABLE 20 : COMPARISON OF LESIONS SCORE AT THIRD WEEK

	P value
GBHC VsPermethrin	p <0.05
GBHC vsIvermectin	**(p <0.001)**
PermethrinVsIvermectin	**(p <0.001)**
Chi square value : 43.948 degree of freedom: 2	

To assess which group had caused statistically significant improvement in severity of lesions - Post hoc analysis with Wilcoxon signed-rank tests was conducted after applying Bonferroni correction, which resulted in a significance level set at p <0.017. Median (IQR) perceived effect levels forthe drug A, drug B and drug C trial were 12.5, 12.00 and 1.5 respectively. Drug B and Drug A lesions score trials revealed no significant differences between these groups (Z = -1.893, p = 0.058). However, there was a statistically significant reduction in lesions severity in the drug C vs drug A trial (Z = -4.790, p = <0.001) and Drug C vs drug B trial (Z= -4.551, p= <0.001).

AT SIXTH WEEK FOLLOW UP:

At the time of second follow up in the sixth week, amelioration in terms of severity of pruritus and severity of lesions in each group were reassessed again to find out the effects of the drug.

i) **SEVERITY SCORE FOR PRURITUS:**

The pruritus severity score of the three groups were compared using Friedman test and the analysis revealed **Chi square value of 52.541 at degree of freedom of 2. p value being less than 0.001** revealed significant difference in pruritus severity scores in the three groups.

Z	Drug A	Drug B	Drug C
Drug A	-NA-	-4.463 **(p<0.001)**	-4.758 **(p<0.001)**
Drug B	-4.463 **(p<0.001)**	-NA-	-4.667 **(p<0.001)**
Drug C	-4.758 **(p<0.001)**	-4.667 **(p<0.001)**	-NA-

TABLE 21 : COMPARISON OF PRURITUS SCORE AT SIXTH WEEK

	P value
GBHC Vs Permethrin	**P<0.001**
GBHC vs Ivermectin	**p <0.001**
Permethrin Vs Ivermectin	**p <0.001**
Chi square value : 52.541 degree of freedom: 2	

To determine which drug had caused significant improvement in severity of pruritus - Post hoc analysis with Wilcoxon signed-rank tests was conducted after applying Bonferroni correction, resulting in a significance level set at $p < 0.017$. Median (IQR) perceived effect levels for drug A, drug B and drug C trial were 3,1 and 0 respectively. There were statistical significant differences between drug B and Drug A lesions score trials ($Z = -4.463$, $p < 0.001$). There was a statistically significant reduction in pruritus severity in the drug C vs drug A trial ($Z = -4.463$, $p = <0.001$) and Drug C vs drug B trial ($Z= -4.758$, $p<0.001$).

ii) **SEVERITY SCORE FOR LESIONS:**

The lesions severity score of the three groups were compared using Friedman test .Statistical analysis revealed **Chi square value of 46.137 at degree of freedom of 2. p value being less than 0.001** revealed significant difference in lesions severity scores in the three groups.

Z	**Drug A**	**Drug B**	**Drug C**
Drug A	-NA-	-4.098**(p: <0.001)**	-4.634**(p: <0.001)**
Drug B	-4.098 **(p: <0.001)**	-NA-	-4.026**(p: <0.001)**
Drug C	-4.634**(p: <0.001)**	-4.026**(p: <0.001)**	-NA-

TABLE 22 : COMPARISON OF LESIONS SCORE AT SIXTH WEEK

	P value
GBHC Vs Permethrin	**P<0.001**
GBHC vs Ivermectin	**p <0.001**
Permethrin Vs Ivermectin	**p <0.001**
Chi square value : 46.137 degree of freedom: 2	

To assess which group had caused statistically significant improvement in severity of lesions - Post hoc analysis with Wilcoxon signed-rank tests was conducted with Bonferroni correction applied, which resulted in a significance level set at p < 0.017. Median (IQR) perceived effect levels forthedrug A, drug B and drug C trial were 6,2 and 0 respectively. Drug B and Drug A lesions score trials revealed significant differences between these groups (Z = -4.098, p = 0.058). However, there was a statistically significant reduction in lesions severity in the drug C vs drug A trial (Z = -4.634, p = <0.001) and Drug C vs drug B trial (Z= -4.026, p= <0.001)

TABLE 23 : COMPARISON OF SEVERITY OF PRURITUS:

	AT PRESENTATION	SECOND WEEK FOLLOW UP	THIRD WEEK FOLLOW UP	SIXTH WEEK FOLLOW UP
A (GBHC)	86.7%	66.7%	10%	0%
B (PERMETHRIN)	90.0%	70%	0%	0%
C (IVERMECTIN)	86.7%	20.6%	0%	0%

In group A (GBHC), there was 20% reduction in the severity score for pruritus at the time of second application. In Group B also there was 20% reduction in the severity score for pruritus during second application. Whereas in Group C there was 66 .1% reduction in the score at time of second application of medication.

TABLE 24 : COMPARISON OF AVERAGE OF PRURITUS IN EACH GROUP AT EACH VISIT

	AT PRESENTATION	SECOND WEEK FOLLOW UP	THIRD WEEK FOLLOW UP	SIXTH WEEK FOLLOW UP
A (GBHC)	10	9	7	5
B (PERMETHRIN)	10	9	6	2
C (IVERMECTIN)	10	4	1	0

This table compares the severity of pruritus in each group at each visit. Average of maximum severity score of pruritus has been taken and tabulated.

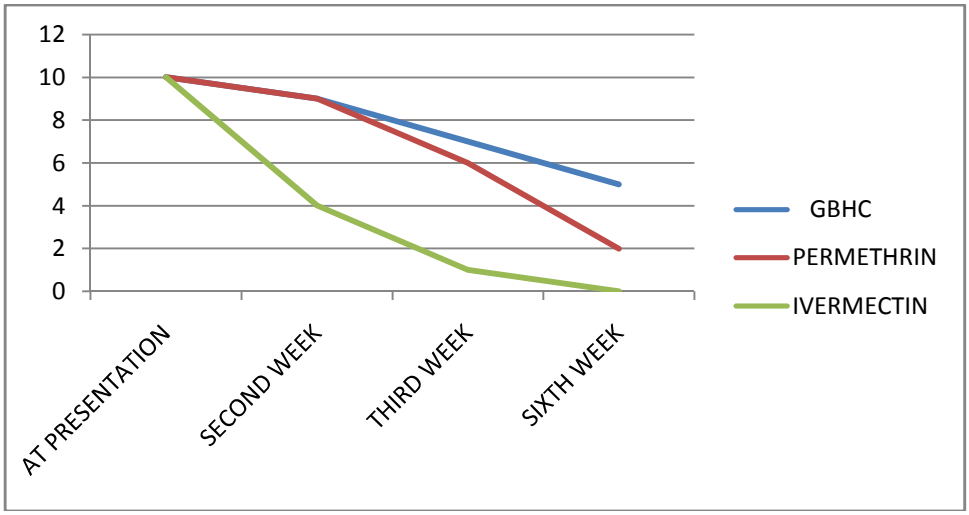


CHART 17 - **COMPARISON OF AVERAGE OF PRURITUS IN EACH GROUP AT EACH VISIT**

The mean Severity of pruritus score across all the treatment groups when compared showed that, patients treated with Ivermectin had the fastest and the maximal response. Both the initial response and the end point was better in Ivermectin group patients. Second best response was seen in permethrin group.

TABLE 25 : COMPARISON OF AVERAGE OF LESIONS IN EACH GROUP AT EACH VISIT:

	AT PRESENTATION	SECOND WEEK FOLLOW UP	THIRD WEEK FOLLOW UP	SIXTH WEEK FOLLOW UP
A (GBHC)	56	45	3	0
B (PERMETHRIN)	54	35	2	0
C (IVERMECTIN)	56	25	0	0

This table compares the severity of lesions in each group at each visit. Average of maximum severity score of lesions has been taken and tabulated.

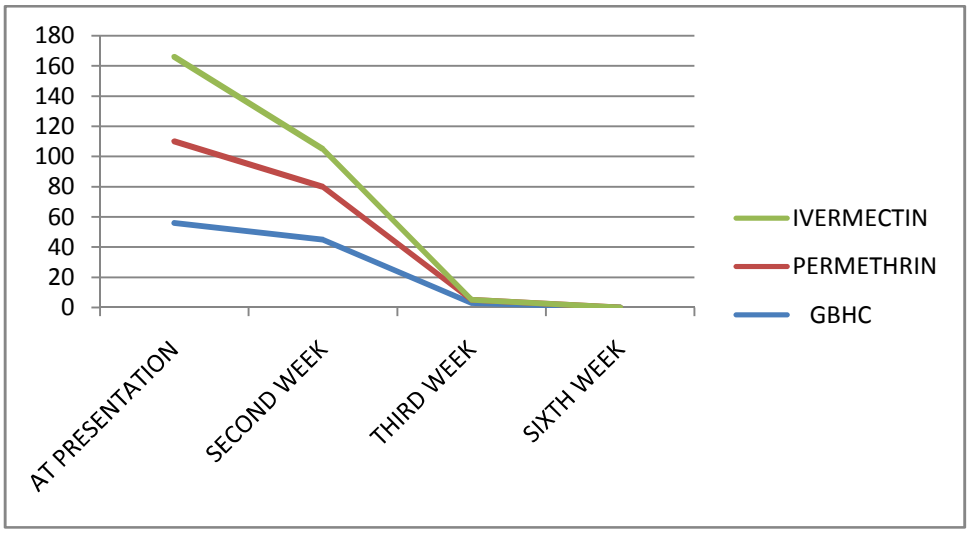


CHART 18 : COMPARISON OF AVERAGE OF LESIONS IN EACH GROUP AT EACH VISIT

The average of Severity of lesions score across all the treatment groups when compared showed that, patients treated with Ivermectin had the fastest response. But later on all the drugs had similar response at the sixth week follow up.

Table 26 : RESPONSE TO TREATMENT IN STUDY GROUPS

TREATMENT GROUP	POOR n (%)	MODERATEn(%)	GOODn(%)
A (GBHC)	10 (33.3%)	17(56.7%)	3(10.0%)
B (PERMETHRIN)	0	19(63.3%)	11(36.7%)
C (IVERMECTIN)	0	4(13.3%)	26(86.6%)

More than 86 % of patients treated with Ivermectin had good response to treatment while only 36.7% % of those treated with permethrin and 3% of those treated with GBHC had good response to treatment. Poor response was seen in 33.3 % of GBHC patients compared to the 0% in patients receiving Permethrin and Ivermectin.

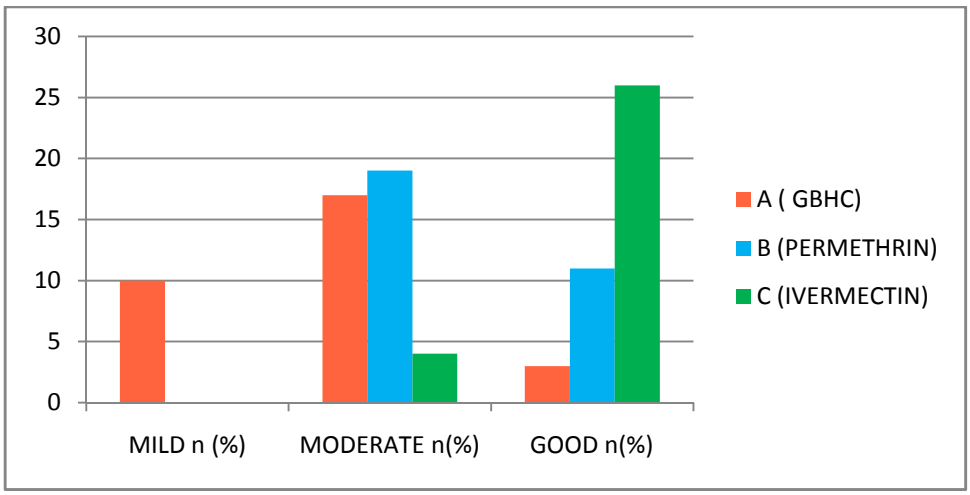


Chart19 : RESPONSE TO TREATMENT IN STUDY GROUPS

SIDE EFFECTS:

No side effects was observed in all the study groups

RELAPSE:

TABLE 27 : RELAPSE IN TREATMENT GROUP

RELAPSE IN TREATMENT GROUP	NO OF PATIENTS n(%)
No relapse	83
Relapse	7

TABLE 28 : RELAPSE IN EACH TREATMENT GROUP

RELAPSE IN TREATMENT GROUP	NO OF PATIENTS n(%)
A(GBHC)	5 (5.6%)
B(PERMETHRIN)	2 (2.2%)
C(IVERMECTIN)	0 (0%)
TOTAL	7 (7.8%)

Out of the 90 patients studied, there was a relapse in 7 (7.8%) of patients.

Out of the 7 relapsed patients, 5 belonged to Group A (GBHC) and 2 patients belonged to Group B (Permethrin). There was no relapse in group C (Ivermectin). Treatment group is significantly associated with relapse. In Group B and Group A, significant association with relapse and treatment group noted with degree of freedom being 2 and at p value of 0.053

RESPONSE TO THE TREATMENT:

On using chi square test for assessing the treatment response, It was found that 86.6% good response was seen in Ivermectin group compared to 36.7% response in Permethrin group and 10% in GBHC group at the time of second application. This is statistically significant with chi square value of 64 and at p value of <0.001 and degree of freedom being 2.

GROUP A

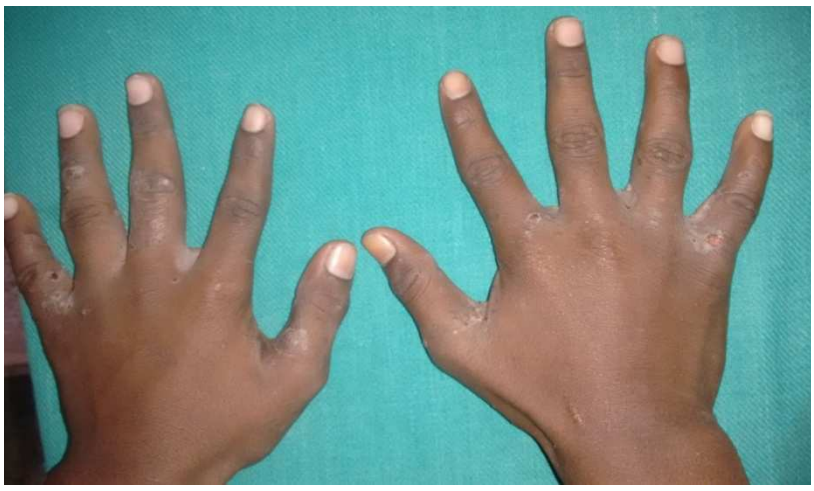
AT PRESENTATION

3rd week follow up

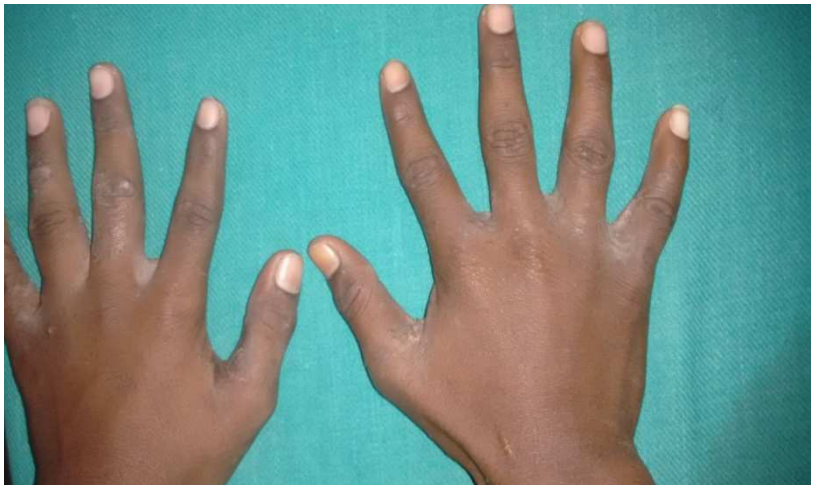
6th week follow up

GROUP B

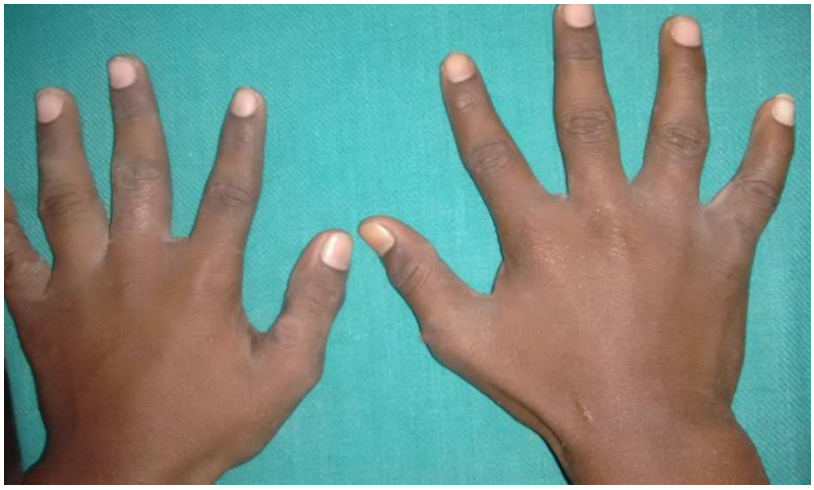
At Presentation



Third week follow up



Sixth week follow up



GROUP C

At presentation

Third week follow up

Sixth week follow up

DISCUSSION

DISCUSSION

This prospective, observational and comparative study was conducted among 90 patients with Scabies presenting to the Out patient Department of Dermatology, Madras Medical College and Rajiv Gandhi Government General Hospital. The study was carried out with a view to compare the efficacy of GBHC, Permethrin and Ivermectin as modalities of treatment for patients with Scabies.

Age of 90 patients ranged from 8 to 52 years. Mean age of the study population was 27.66 years and standard deviation 13.213 years. Forty seven patients were males (52.2%) and forty three patients were females (47.8%).

Amidst the study group, 18 patients were under the age of 14 years. Of that 6 patients each were treated with GBHC, Permethrin and Ivermectin. GBHC and Ivermectin group comprised of 3 males and 3 females each whereas Permethrin group comprised of 4 male children and 2 female children.

Out of 90 patients, 62 (68.9%) patients were from urban area and 28 (31.1%) patients were from rural area.

Among 90 patients, forty patients (44.4%) patients belonged to Class IV socioeconomic status (according to modified Kuppuswamy scale) and 31 (34.4 %) patients belonged to Class V (according to modified Kuppuswamy scale). Scabies was most common in lower socioeconomic group in our study group and more common among urban area. The probable reason would have been overcrowding and poor sanitation.

Forty seven patients (52.2 %) presented with symptoms of duration more than 15 days whereas 37 (41.1%) patients presented between eight to fourteen days of symptoms and six patients (6.7%) presented within a week. Only primary scabies cases were included in the study.

In our study group, among 90 patients, inmates i.e. house hold contacts, family members, close contacts of nearly 69 patients (76.7%) were affected whereas among 21 patients (23.3%), inmates were not affected.

In the study population, out of 90 patients, 17 patients, that is 18.8 % had associated secondary infections.

Out of the 90 patients studied, 8 (8.88%) patients had associated dermatophyte infection and 17 (18.8%) patients had associated secondary infection and others had no associated skin manifestations.

Scabies was found in high frequency among O positive individuals- 34 (38 %) patients in our group. Second most common blood group observed was B positive- 25 (27.7%) patients.

Nearly 7 patients (7.7%) were found out to be positive for Human Immunodeficiency Virus (HIV) infection. Out of the seven HIV positive individuals, six were males and one was female.

The 90 patients in the study were divided into three groups of 30 patients each and started on respective treatment regimen. In GBHC group, there were 16 male patients and 14 female patients. In Permethrin group, there were 15 male patients and 15 female patients. In Ivemectin group, there were 16 male patients and 14 female patients.

The treatment response was analysed in all the treatment groups based on reduction in the Severity of pruritus score and Severity of Lesions score. The response was then graded as good, moderate and poor.

Among the thirty patients treated with GBHC, three patients (10%) had good response to treatment, with seventeen patients (56.7%) showing moderate response and ten patients (33.3%) showed poor response to treatment.

Of the thirty patients managed with permethrin, eleven patients (36.7%) patients showed good response to treatment. Nineteen patients (63.3%) showed moderate response to treatment with permethrin.

In patients treated with Ivermectin group, twenty six patients (86.6%) showed good response to treatment whereas only four patients (13.3%) showed moderate response to treatment.

Ivermectin compared favourably to the other two drugs with nearly more than three fourths of the patients having significant symptomatic improvement and improvement in lesions at an earlier stage. While Permethrin group had better response after twice application of medicine when compared to GBHC group

Age and sex seemed to have no effect on the response to treatment, with patients across all age groups showing same pattern of response in all the three treatment groups.

On analysing the severity of pruritus and severity of lesions scores, the Ivermectin group patients showed the maximal reduction in Severity of Pruritus and severity of lesions score between baseline and second application and at

third week follow up. The value at second week after first application of medicine was significant with a drop of more than eighty six percentage (86%) seen in patients.

Permethrin group patients also had a higher reduction in Severity of pruritus score and severity of lesions score soon after completion of second application of medicine. At the time of third week follow up after second application of medicine, patients showed more than 90% improvement in symptoms and disease.

In the GBHC group, the initial response is lower than that of Ivermectin and Permethrin with decrease in only 20% of lesions at the time of second application of medicine. While at the time of third week follow up, there was nearly 76.7% improvement in skin lesions.

The end points are comparable in each response group separately. Ivermectin group had earlier improvement in symptoms and cutaneous signs with nearly 86.7% reduction in severity of pruritus score and 87.8% reduction in severity of lesions score soon after a week of first application.

In permethrin group and GBHC group, the initial response was 20% reduction in the severity of pruritus and lesions score at the time of second week follow up after first application, whereas at the time of third week follow up after second application of medicine, Permethrin group had 70% reduction in severity of pruritus and lesions score while GBHC group had only 56.7% improvement of severity of pruritus and lesions scores.

None of these patients surprisingly showed any signs of adverse effects. Out of the 90 patients studied, there was a relapse in 7 (7.8%) of patients.

Out of the 7 relapsed patients, 5 belonged to Group A (GBHC) and 2 patients belonged to Group B (Permethrin). There was no relapse in group C (Ivermectin).

In Goldust et al[99]study, it was shown that topical ivermectin was more effective than Crotamiton 10% cream when used twice over a period of four weeks which correlates with our study showing much better response when compared to other scabicidal agents in our treatment groups.

In 1986, Taplin *et al*[100]**.** showed a cure rate of 91% for permethrin in comparison with 65% for lindane in treating scabies at 4-week post-treatment. In another trial, Schultz *et al.* reported cure rates of 91% and 86.3% with permethrin and lindane, respectively. These two studies correlates with our studies as in our study permethrin has shown cure rate of more than 90%.

LIMITATIONS OF STUDY

This study was not large enough to be of reasonable precision as it has been carried out over a limited period of time with a limited number of patients. All the available modalities of treatment were not assessed. All the facts and figures mentioned here might considerably vary from those of large series covering wide range of time, but still then, as the cases of this study were collected from a tertiary level hospital in our country, this study has some credentials in reflecting the facts regarding the available treatment options and the most favourable modality of treatment for patients.

SUMMARY

Scabies is a common cutaenous infestation affecting the population of any age but more common in young individuals. It is a distressing disease encountered frequently in clinical practice. The current mainstay of therapy is the use of topical permethrin and oral ivermectin along with anti-histamines. However, topical ivermectin is a newer drug which can be used in scabies patients.

In our study we have compared the efficacy of GBHC, Permethrin and Ivemectin in the treatment of Scabies. The following conclusions were reached.

Age and Sex Distribution :

Young individuals were the most commonly involved group. Children and young individuals in the age group of 16-25 was the susceptible age group. There was no significant difference gender wise. This is in accordance with other Indian studies regarding the epidemiology of the disease.

Socioeconomic status:

Scabies was most common among lower socioeconomic status (according to Modified Kuppuswamy scale)in the study group which correlates with other Indian studies.

Place of residence:

Scabies was most common among patients from urban area in our study group.

Prevalence of Secondary skin infection :

Out of 90 patients in the study, 17 patients turned out to have secondary bacterial infections. This suggests that secondary infections are common among scabies patients.

Prevalence of associated cutaneous diseases :

In our study group, secondary bacterial infection was the most common associated cutaneous disease. Next common disease observed was dermatophyte infection.

Prevalence of HIV infection :

In our study group, HIV infection was found to be present in 7 out of 90 patients. Out of it six were males and one was a female.

Comparison of the treatment groups :

In the Ivermectin group, all patients had a significant reduction in their Severity of Pruritus and severity of lesions score, with only four patients having moderate response, which was explained by the fact that both those patients had a severe initial presentation. This response to Ivermectin was found to be in concurrence with studies by **Goldust et al** study. There was no evidence of relapse.

In the Permethrin group, again there was a significant improvement in response compared to the GBHC group, but they compared unfavourably with Ivermectin group. The initial response was slower than that of Ivermectin but the end point was similar especially in those responding well to treatment.

There was no evidence of side effect but there was relapse in 2 patients. These findings had concordance with studies conducted by **Taplin et al and Schultz et al.**

In the GBHC group, there was a comparatively slower reduction in the Severity of pruritus score and severity of lesions with response starting only after the second application of medicine .No side effects was observed in this group too. But there was relapse in 5 patients of our study group.

CONCLUSION

CONCLUSIONS

The following recommendations may be suggested on the basis of the findings of the study :

1. Topical Ivermectin can be considered as first line of treatment modality for scabies as it shows earlier and maximal response when compared to other two drugs-permethrin and GBHC.

2. Topical permethrin gives better improvement when compared to that of GBHC and hence can be considered as better modality of treatment when compared to GBHC.

3. Severity of lesion score has reduced earlier and to maximum in our study with topical ivermectin.

4. Severity of pruritus score has reduced earlier and maximum in our study with the use of topical ivermectin.

5. Children are a source of infection as they have presented late compared to the adults. Hence screening of children in schools is mandatory for early detection of scabies to prevent spread of infection.

6. The severity and duration of symptoms are more in elderly. It is essential to differentiate it from senile pruritus and to treat for scabies.

7. HIV patients have shown poor response to treatment. They are more prone for secondary infection. So early recognition of disease and treatment is needed in them.

8. Face involvement can be present in children, elderly individuals and HIV patients.

9. Routine screening for scabies is important in persons belonging to lower socioeconomic status especially in those living in urban areas.

10. Secondary bacterial infection is more common in children and HIV affected individuals. Hence early recognition and treatment is important in these patients.

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BIBLIOGRAPHY

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ANNEXURES

ABBREVIATIONS

ELISA	-	Enzyme Linked Immuno Sorbent Assay
PCR	-	Polymerase Chain Reaction
HIV	-	Human Immunodeficiency Virus
GBHC	-	Gamma Benzene Hexa Chloride
GABA	-	Gamma Amino Butyric Acid
Ig E	-	Immunoglobulin E

PROFORMA

Case No :

PATIENT DETAILS:

Name : Age : Sex: OP No :

Address : Occupation :

Housing: No of rooms:

Number of members in the house:

Main Complaints:

H/O present illness;

- Duration of illness
- Sites involved
- Progression

H/O worsening of itching in the night

H/O itching in the family / inmates

H/O contact with pet animals

H/O insect bite

H/O drug intake prior to onset of lesions

H/O treatment for scabies in the past

H/O any systemic illness

H/O any drug allergy

Associated dermatological disorders: Impetigo

Cellulitis

Furuncle

Pyoderma

CLINICAL EXAMINATION:

General examination :

Generalised lymphadenopathhy

Pulse : /min BP : / mm of Hg RR : /min Temp :

Pallor : Icterus :

CVS :

RS :

P/A :

CNS:

Bones and joints:

DERMATOLOGICAL EXAMINATION:

Site of involvement:

Palms and soles:

Oral and genital Mucosa:

Hair and nail:

INVESTIGATIONS:

Skin scrapings/ Finger nail scraping for microscopy with 10% Potassium Hydroxide

TREATMENT :

Group :

Regimen given:

FOLLOW UP:

Onset of remission:

Duration of remission:

Side effects:

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003

EC Reg.No.ECR/270/Inst./TN/2013
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CERTIFICATE OF APPROVAL

To
Dr.R.Rajalakshmi
IInd Year P.G. in MD DVL
Madras Medical College/RGGGH
Chennai 600 003

Dear Dr.R.Rajalakshmi ,

The Institutional Ethics Committee has considered your request and approved your study titled " **EFFICACY OF TOPICAL IVERMECTIN IN COMPARISON TO OTHER SCABICIDAL AGENTS " - NO.18012016.**

The following members of Ethics Committee were present in the meeting hold on **05.01.2016** conducted at Madras Medical College, Chennai 3

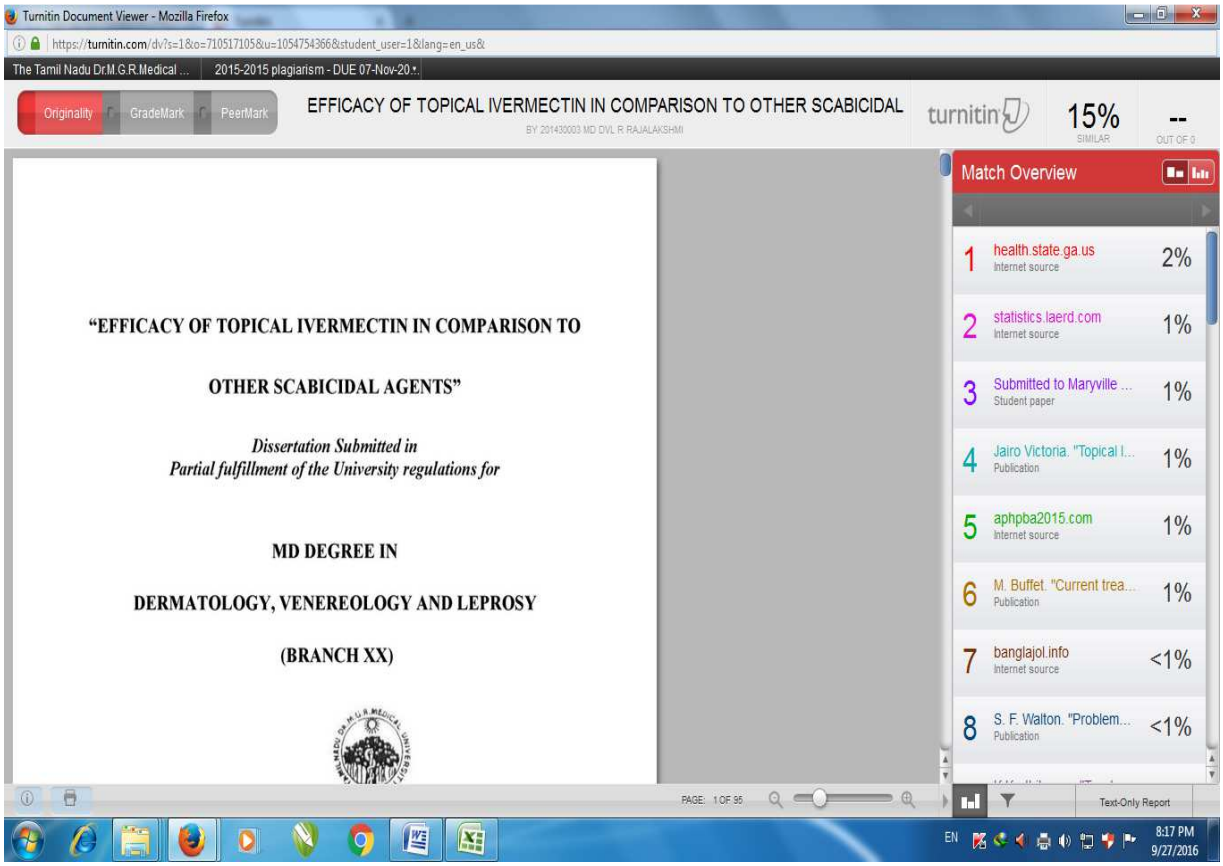
1.Dr.C.Rajendran, MD.,	:Chairperson
2.Dr.R.Vimala,MD.,Dean,MMC,Ch-3	:Deputy Chairperson
3.Prof.Sudha Seshayyan,MD., Vice Principal,MMC,Ch-3	: Member Secretary
4.Prof.B.Vasanthi,MD.,Inst.of Pharmacology,MMC,Ch-3	: Member
5.Prof.Md.Ali,MD.,DM.,HOD-MGE, MMC,Ch-3	: Member
6.Prof.K.Ramadevi,MD, Director, Inst. of Bio-Chem,MMC,Ch-3	: Member
7.Prof.M.Saraswathi, MD.,Director, Inst.of Path,MMC,Ch-3	: Member
8.Prof.Srinivasagalu,MD.Director,Inst.of Int.Med.MMC,Ch-3	:Member
9.Tmt.J.Rajalakshmi,JAO,MMC,Ch-3	: Lay Person
10.Thiru S.Govindasamy, BA.,BL,High Court,Chennai	: Lawyer
11.Tmt.Arnold Saulina, MA.,MSW.,	:Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

MADRAS MEDICAL COLLEGE
21 JAN 2016
CHENNAI-600 003

Member Secretary – Ethics Committee
MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003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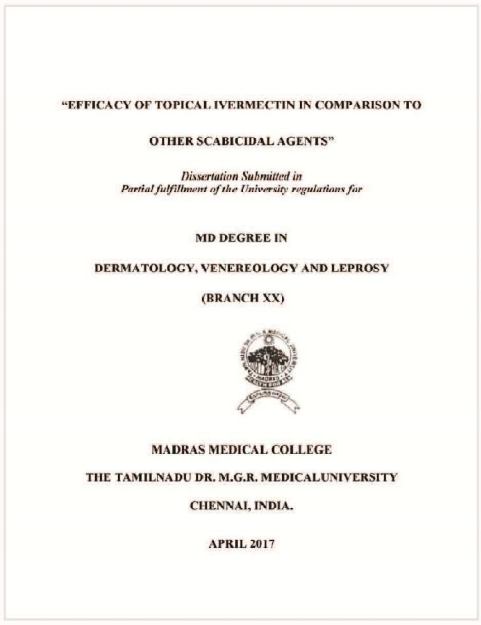

"EFFICACY OF TOPICAL IVERMECTIN IN COMPARISON TO

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(BRANCH XX)

MADRAS MEDICAL COLLEGE

THE TAMILNADU DR. M.G.R. MEDICALUNIVERSITY

CHENNAI, INDIA.

APRIL 2017

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INFORMATION SHEET

TITLE : "EFFICACY OF TOPICAL IVERMECTIN IN COMPARISON TO OTHER SCABICIDAL AGENTS"

Name of Investigator : Dr.R.Rajalakshmi

Name of Participant :

Purpose of Research : The purpose of this study is to determine the efficacy of Ivermectin in comparison to other scabicidal agents.

Study Design : Prospective Observational Study

Study Procedures : In this study patient's history will be taken, examination and mineral oil application/ burrow ink application will be done. Scraping will be done from burrows for microscopic examination with 10% KOH. The patients are then randomly grouped into 3 groups and patients will be treated with topical permethrin/ topical 1%GBHC or topical 0.5% ivermectin.

Possible Risks : No risks to the patient

Possible benefits:

To patient : The patient will be provided with any of the above mentioned treatments for scabies

To doctor & to other people : The results of the study will help to determine the most effective treatment for Scabies. This will help in providing better and complete treatment to other patients in future.

Confidentiality of the information obtained from you :

The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Can you decide to stop participating in the study :

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time.

How will your decision to not participate in the study affect you :

Your decision will not result in any loss of benefits to which you are otherwise entitled.

Signature of Investigator Signature of Participant

Date :

Place :

ஆராய்ச்சி தகவல் தாள்

ஆராய்ச்சியாளர்கள் : டாக்டர் இரா. இராஜலஷ்மி

: டாக்டர் க.மனோகரன்

: டாக்டர் சாமுஎல் ஜெயராஜ் டேனியல்

பங்கேற்பாளரின் பெயர்

தலைப்பு : **சொறிசிரங்கு நோயின் சிகிச்சை முறைகளின் பலன்களை ஒப்பிடுவதற்கான ஆய்வு**

தங்களை இந்த ஆராய்ச்சியில் பங்கேற்குமாறு கேட்டுக்கொள்கிறேன். இந்த படிவத்தில் உள்ள தகவல் மூலமாக இந்த ஆராய்ச்சியில் பங்கு கொள்ளலாமா என்பதை தயக்கமும் இன்றி கேட்டுக்கொள்ளலாம்.

ஆய்வின் நோக்கம்:

சொறி சிரங்கு நோய்க்கான சில சிகிச்சை முறைகளின் பலன்களை ஒப்பீடு செய்வது.

ஆய்வு முறைகள்

விரிவான நோய்க்குறிப்புகளும், மருத்துவ பரிசோனைகளும் செய்யப் படும். நோயாளிகள் மூன்று குழுக்களாக (Group 1,2,3) தன்னிச்சையாக பிரிக்கப்படுவர்.

Group I ஐவர்மெக்டின் குழு (Ivermectin):

இக்குழுவினர் ஒரு நாள் இரவு மட்டும் குளித்த பிறகு ஐவர்மெக்டின் மருந்தை கழுத்தில் தொடங்கி உடல் முழுவதும் (முகத்தை தவிர) முக்கியமாக விரல் இடுக்குகள், அக்குள், தொடை இடுக்குகளிலும் தடவுமாறு அறிவுறுத்தப் படுவார்கள். பின்னர் காலையில் குளிக்குமாறு அறிவுறுத்தப் படுவார்கள்.

Group II பெர்மெத்ரின் குழு (Permethrin):

இக்குழுவினர் ஒரு நாள் இரவு மட்டும் குளித்த பிறகு பெர்மெத்ரின் மருந்து கழுத்தில் தொடங்கி உடல் முழுவதும் (முகத்தை தவிர) முக்கியமாக விரல் இடுக்குகள், அக்குள், தொடை இடுக்குகளிலும் தடவுமாறு அறிவுறுத்தப் படுவார்கள். பின்னர் காலையில் குளிக்குமாறு அறிவுறுத்தப் படுவார்கள்.

Group III ஜி.பி.எச்.சி. குழு (GBHC):

இக்குழுவினர் ஒரு நாள் இரவு மட்டும் குளித்த பிறகு ஜி.பி.எச்.சி. மருந்து கழுத்தில் தொடங்கி உடல் முழுவதும் (முகத்தை தவிர) முக்கியமாக விரல் இடுக்குகள், அக்குள், தொடை இடுக்குகளிலும் தடவுமாறு அறிவுறுத்தப் படுவார்கள். பின்னர் காலையில் குளிக்குமாறு அறிவுறுத்தப் படுவார்கள்.

ஆய்வினால் மக்களுக்கு ஏற்படும் நன்மைகள்:

இந்த ஆய்வின் முடிவில் கிடைக்கும் தகவல்கள் சமுதாயத்திற்கு பயனுள்ளதாகவும், எதிர்காலத்தில் நோயாளிகளுக்கு மருத்துவ தீர்வாகவும் அமையும்.

தங்களிடமிருந்து பெறப்படும் தகவல்களின் நம்பகத்தன்மை

தங்களிடமிருந்து பெறப்படும் தகவல்கள் பாதுகாக்கப்படுவதற்கான முழு உரிமையும் தங்களக்கு உண்டு.

PATIENT CONSENT FORM

Title of the study : "EFFICACY OF TOPICAL IVERMECTIN IN COMPARISON TO OTHER SCABICIDAL AGENTS"

Name of the Participant:

Name of the Principal investigator: Dr.R. RAJALAKSHMI

Name of the Institution : Rajiv Gandhi Government General Hospital, Chennai

Documentation of the informed consent

I _____ have read the information in this form (or it has been read for me). I was free to ask any questions and they have been answered. I hereby give my consent to be included or to include my child _____ as a participant in the study.

1. I have read and understood this consent form and the information provided to me.

2. I have had the consent document explained to me.

3. I have been explained about the nature of the study.

4. My / my child's rights and responsibilities have been explained to me by the investigator.

5. I have informed the investigator of all the treatments I am / my child is taking or have taken in the past 1 year including any native (alternative) treatment.

6. I agree to cooperate with the investigator and I will inform her immediately if I / my child suffer unusual symptoms.

7. I / my child have not participated in any research study at any time .

8. I am aware of the fact that I / my child can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital.

9. I hereby give permission to the investigators to release the information obtained from me as a result of participation in this study to the sponsors, regulatory authorities,Govt agencies and IEC.I understand that they are publicly presented.

10. My / my child's identity will be kept confidential if my data are publicly presented.

11. I have had my questions answered to my satisfaction.

12. I have decided to be included / include my child in the research study

13. I am aware that if I have any question during this study, I should contact at one of the addresses listed above. By signing this consent form I attest that the information given in this document has been clearly explained to me and apparently understood by me. I will be given a copy of this consent document.

Participant's / Parent's initials:_____

For adult participants:

Name and signature/thumb impression of the Participant (or) Parent (or legal representative if participant incompetent)

_____ _____ _____

Name Signature Date

Name and signature of impartial witness (required for illiterate patients):

_____ _____ _____

Name Signature Date

Address and contact number of the impartial witness:

Name and Signature of the investigator or his representative obtaining consent:

_____ _____ _____

Name Signature Date

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சியின் தலைப்பு :

சொறிசிரங்கு நோயின் சிகிச்சை முறைகளின் பலாபலன்களை ஒப்பிடுவதற்கான ஆய்வு.

ஆராய்ச்சி செய்பவரின் பெயர் : மருத்துவர். இரா. இராஜலஷ்மி

ஆராய்ச்சி மையம் : ராஜீவ் காந்தி அரசு பொது மருத்துவமனை
சென்னை-600003.

..... எனும் நான், எனக்கு கொடுத்துள்ள தகவல் தாளைப் படித்து புரிந்து கொண்டேன். நான் இந்த ஆராய்ச்சியில் என்னை / எனது குழந்தையை ..... சேர்த்துக் கொள்ள சம்மதிக்கிறேன்.

1. நான் எனக்கு அளிக்கப்பட்ட ஒப்புதல் படிவத்தையும், தகவல்களையும் படித்து புரிந்து கொண்டேன்.
2. ஒப்புதல் படிவத்தில் உள்ள தகவல்கள் எனக்கு விளக்கிக் கூறப்பட்டன.
3. ஆய்வின் தன்மை பற்றி எனக்கு விளக்கப்பட்டது.
4. என்னுடைய / எனது குழந்தையின் உரிமைகளையும், பொறுப்புகளையும் ஆராய்ச்சியாளர் விளக்கிக் கூறினார்.
5. நான் அல்லது எனது குழந்தை இதுவரை எடுத்துள்ள / எடுத்து கொண்டிருக்கும் அனைத்து விதமான சிகிச்சை முறைகளையும் ஆராய்ச்சியாளரிடம் கூறியுள்ளேன்.
6. இந்த ஆராய்ச்சியினால் ஏற்படும் தீமைகள் பற்றி விளக்கப்பட்டன.
7. நான் ஆராய்ச்சியாளருடன் ஒத்துழைப்பேன் என்றும் எனக்கு அல்லது எனது குழந்தைக்கு ஏற்படக்கூடிய அசாதாரணமான நிகழ்வுகள் பற்றியும் உடனடியாக ஆராய்ச்சியாளரிடம் தெரிவிப்பேன் என்றும் உறுதி கூறுகிறேன்.
8. நான் / எனது குழந்தை கடந்த ..... மாதங்களாக எந்தவிதமான ஆய்வுகளிலும் பங்கேற்கவில்லை.
9. எனக்கு அல்லது எனது குழந்தைக்கு செய்யப்படும் அனைத்து பரிசோதனைகளும் (உதாரணம் : இரத்தம் எடுத்தல்) என் நோயின் தன்மையை அறிவதற்காக செய்யப்படுபவை என்பதை அறிகிறேன்.

10. இந்த ஆய்விலிருந்து எப்போது வேண்டுமானாலும் எக்காரணமும் கூறாமல் நான் என்னை / எனது குழந்தையை விடுவித்துக் கொள்ளலாம் என்பதை அறிவேன் மற்றும் இதனால் எனக்கு அல்லது எனது குழந்தைக்கு தரப்படும் சிகிச்சைக்கு எந்த பாதிப்பும் வராது என்பதை அறிவேன்.

11. ஆராய்ச்சியாளர்கள் இந்த ஆய்வில் எனது அல்லது எனது குழந்தையின் பங்களிப்பை எந்த நேரத்திலும் எக்காரணமும் கூறாமல் என் சம்மதம் இல்லாமலும் என்னை அல்லது எனது குழந்தையை விலக்கிவிட முடியும் என்பதை அறிவேன்.

12. என்னிடம் இருந்து பெறப்படும் தகவல்களை அரசு, வரைமுறை அதிகாரிகள் ஆகியோர்களுடன் பகிர்ந்து கொள்ள ஆராய்ச்சியாளர்களுக்கு அனுமதி அளிக்கிறேன். என்னுடைய தஸ்தாவேஜுகளை பார்வையிட அவர்களுக்கு உரிமை உண்டு.

13. என்னிடம் பெறப்படும் தகவல்கள் பொதுவாக பரிசுரிக்கப்பட்டாலும், என்னுடைய / எனது குழந்தையின் அடையாளம் இரகசியமாக வைக்கப்படும் என்பதை அறிவேன்.

14. எனக்கு திருப்தி அளிக்கும் வகையில் என்னிடம் கேட்கப்பட்ட கேள்விகளுக்கு நான் பதில் அளித்துள்ளேன்.

15. இந்த ஆராய்ச்சியில் நான் அல்லது எனது குழந்தையை பங்கேற்க தன்னிச்சையாக முழுமனதுடன் நான் சம்மதிக்கிறேன்.

இந்த ஆய்வின் போது எனக்கு என்ன சந்தேகம் ஏற்பட்டாலும் ஆராய்ச்சியாளரை தொடர்பு கொள்ளலாம் என்பதை அறிவேன்.

இந்த ஒப்புதல் படிவத்தில் கையெழுத்திடுவதன் மூலம் இங்கு தரப்பட்டிருக்கும் அனைத்து தகவல்களும் தெளிவாகக் கூறப்பட்டு என்னால் முழுமையாக புரிந்து கொள்ளப்பட்டது என்பதை சான்றளிக்கிறேன். இந்த ஒப்புதல் படிவத்தின் நகல் என்னால் பெற்றுக் கொள்ளப்பட்டது.

பங்கேற்பவர்/பங்குபெறுபவரின் பெற்றோர் கையொப்பம்

இடம் :

கட்டைவிரல் ரேகை :

தேதி :

பங்கேற்பவரின் பெயர் :
விலாசம் :

ஆய்வாளரின் பெயர் :

இடம் :

தேதி :

MASTER CHART

Sl No	NAME	AGE	SEX	OP NO	RURAL (R) / URBAN (U)	OCCUPATION	SOCIO-ECONOMIC STATUS	No. OF ROOMS	No. OF INMATES	INMATES AFFECTED	DURATION (In days)	SITES AFFECTED Hands-H, Axilla-A, Groin-G, trunk-T, Limbs-L	AT PRESENTATION							BLOOD GROUP	HIV	TREATMENT	SECOND APPLICATION				AT FIRST WEEK				AT FOURTH WEEK				Adverse effect	Response	Relapse
													Severity of Pruritus		SEVERITY OF LESIONS		SECONDARY INFECTION	Associated skin diseases	LYMPH NODES				Severity of Pruritus		Severity of Lesions		Severity of Pruritus		Severity of lesions		Severity of Pruritus		Severity of lesions				
													No	Grad	No	Grade							No	Grade	No	Grade	no	grad	No	Grade	no	grade	No	Grade			
1	KOTEESWARAN	18	M	154632	U	LABOURER	5	1	4	YES	20	H A G T L	10	3	40	2	NO	NO	NO	A +ve	Negative	1% GBHC	7	3	32	2	6	2	20	2	3	1	6	1	NIL	MODERATE	nil
2	PRASANTH	14	M	143526	U	STUDENT	3	2	4	YES	14	H A G T	8	3	42	2	NO	NO	NO	O +ve	Negative	5% Permethrin	6	2	28	2	4	2	10	1	1	1	0	0	NIL	GOOD	NIL
3	RAMU	10	M	178564	U	STUDENT	3	2	5	YES	14	H G T L	7	3	50	3	NO	NO	NO	O +ve	Negative	0.5% Ivermectin	4	2	23	2	1	1	10	1	0	0	0	0	NIL	GOOD	NIL
4	SENTHAMILSELVI	32	F	145786	U	HOUSEWIFE	4	2	3	NO	18	H A G T L	10	3	52	3	NO	NO	NO	A +ve	Negative	1% GBHC	8	3	45	2	7	3	35	2	6	2	8	2	NIL	MILD	NIL
5	SALSA	50	F	109876	U	LABOURER	5	2	3	NO	21	H A G T L	6	3	39	2	no	TINEA	ENLARGE	B +ve	Negative	5% Permethrin	6	2	25	2	4	2	10	1	1	1	0	0	NIL	GOOD	NIL
6	VIMAL	18	M	134256	R	STUDENT	3	1	4	YES	10	H A G T L	6	3	50	3	NO	NO	NO	O +ve	Negative	0.5% Ivermectin	4	2	23	2	1	1	10	1	0	0	0	0	NIL	GOOD	NIL
7	DHANASEKAR	14	M	187962	R	STUDENT	4	2	5	YES	10	H G T L	9	3	50	3	NO	NO	NO	A +ve	Negative	1% GBHC	7	3	30	2	5	2	14	2	3	1	6	1	NIL	MODERATE	PRESENT
8	SATISH	28	M	154367	U	LABOURER	4	2	5	YES	21	H A G T L	6	3	35	2	NO	NO	NO	A +ve	Negative	5% Permethrin	9	3	21	2	5	2	12	2	1	1	2	1	NIL	GOOD	NIL
9	SHANKAR	27	M	150983	U	LABOURER	4	2	6	YES	15	H A G T	4	3	54	3	NO	NO	NO	O +ve	Negative	0.5% Ivermectin	4	2	25	2	1	1	12	2	0	0	0	0	NIL	GOOD	NIL
10	SIVA	12	M	245637	U	STUDENT	5	1	4	YES	12	H A G T L	9	3	36	2	no	NO	NO	O +ve	Negative	1% GBHC	7	3	24	2	5	2	15	2	5	2	9	1	NIL	MILD	NIL
11	MADHUMI THA	8	F	235673	U	STUDENT	3	1	3	YES	10	H A G T L	7	3	32	2	NO	NO	NO	O +ve	Negative	5% Permethrin	5	2	18	2	3	1	10	1	1	1	2	1	NIL	GOOD	NIL
12	SEKAR	39	M	136785	U	LABOURER	4	3	4	NO	8	H A G T L	7	3	48	2	NO	NO	NO	O +ve	Negative	0.5% Ivermectin	3	1	20	2	1	1	9	1	0	0	0	0	NIL	GOOD	NIL
13	DHANASEKARAN	14	M	236547	U	STUDENT	4	1	3	YES	10	H A G T L	10	3	26	2	NO	tinea cruri	NO	B+ve	Negative	1% GBHC	6	2	15	2	4	2	8	1	5	2	2	1	NIL	MODERATE	NIL
14	VAMSIKRISHNA	16	M	125678	U	STUDENT	4	1	3	YES	9	H A G T	7	3	54	3	NO	NO	NO	A +ve	Negative	5% Permethrin	7	3	35	2	4	2	26	2	2	1	5	1	NIL	MODERATE	NIL
15	SWETHA	14	F	298567	R	STUDENT	3	1	4	YES	10	H A G T L	5	3	45	2	YES	NO	YES	O +ve	Negative	0.5% Ivermectin	3	1	18	2	0	0	6	1	0	0	0	0	NIL	GOOD	NIL
16	JAMEEL	24	M	342512	U	LABOURER	5	1	5	YES	18	H G T L	10	3	52	3	NO	NO	NO	A +ve	Negative	1% GBHC	6	2	25	2	4	2	12	2	5	2	8	1	NIL	MILD	NIL
17	PRADEEP	21	M	127645	U	LABOURER	5	1	4	YES	14	H A G T L	9	2	30	2	NO	NO	NO	O +ve	Negative	5% Permethrin	5	2	16	2	4	2	8	1	1	1	0	0	NIL	GOOD	NIL
18	SINDHU	19	F	178563	U	STUDENT	2	1	4	YES	15	H A G T	7	3	42	2	NO	TINEA	NO	O +ve	Negative	0.5% Ivermectin	4	2	18	2	0	0	2	1	0	0	0	0	NIL	GOOD	NIL
19	KAVIYARASI	18	F	134251	U	STUDENT	4	1	3	YES	19	H G T L	10	3	35	2	NO	NO	NO	A +ve	Negative	1% GBHC	7	3	24	2	6	2	15	2	5	2	8	1	NIL	MILD	NIL
20	ANBARASI	19	F	135689	U	LABOURER	4	1	3	YES	14	H A G T L	7	3	40	2	YES	NO	YES	B+ve	Negative	5% Permethrin	7	3	25	2	5	2	12	2	1	1	2	1	NIL	MODERATE	NIL
21	KAMALA	33	F	136543	R	LABOURER	5	2	3	NO	18	H A G T L	6	3	40	2	NO	NO	NO	O +ve	Negative	0.5% Ivermectin	3	1	15	2	1	1	1	1	0	0	0	0	NIL	GOOD	NIL
22	MOHAN	21	M	197834	U	LABOURER	5	1	5	YES	10	H A G T L	10	3	36	2	NO	NO	NO	O +ve	Negative	1% GBHC	6	2	20	2	4	2	12	2	2	1	5	1	NIL	MODERATE	NIL
23	AKASH	13	M	156732	U	STUDENT	3	1	3	YES	10	H G T L	6	3	36	2	NO	NO	NO	O +ve	Negative	5% Permethrin	7	3	22	2	3	1	12	2	1	1	2	1	NIL	MODERATE	NIL
24	MURTHY	47	M	108456	U	LABOURER	5	3	4	NO	21	H A G T	5	3	54	3	YES	NO	YES	A +ve	positive	0.5% Ivermectin	4	2	23	2	1	1	4	1	0	0	0	0	NIL	MODRATE	NIL
25	PRABHU	23	M	197643	R	LABOURER	4	1	3	YES	21	H A G T L	6	2	20	2	NO	NO	NO	AB+ve	Negative	1% GBHC	4	2	12	2	3	1	3	1	0	0	0	0	NIL	GOOD	PRESENT

26	PAPPUKUMARI	23	F	142367	U	LABOURER	4	1	2	YES	15	H A G T L	8	3	54	3	NO	NO	NO	B +ve	Negative	5% Permethrin	7	3	24	2	5	2	14	2	1	1	2	1	NIL	MODERATE	NIL
27	VIJAYA	42	F	126436	R	LABOURER	5	3	5	YES	18	H G T L	8	2	30	2	YES	NO	NO	B +ve	Negative	0.5% Ivermectin	2	1	9	1	0	0	2	1	0	0	0	0	NIL	GOOD	NIL
28	KALIMUTHU	34	M	176235	U	LABOURER	4	1	4	YES	15	H A G T L	9	3	35	2	NO	NO	NO	B+ve	Negative	1% GBHC	6	2	22	2	2	1	12	2	2	1	4	1	NIL	MODERATE	NIL
29	ATUL	10	M	196742	U	STUDENT	3	1	3	YES	7	H A G T L	8	3	46	2	NO	NO	NO	O +ve	Negative	5% Permethrin	7	3	25	2	5	2	15	2	1	1	2	1	NIL	MODERATE	NIL
30	RAMESH	20	M	127850	R	LABOURER	4	1	3	YES	19	H A G T	8	3	36	2	YES	NO	YES	O +ve	Negative	0.5% Ivermectin	3	1	15	2	1	1	2	1	0	0	0	0	NIL	GOOD	NIL
31	PRIYA	14	F	142567	U	STUDENT	3	1	4	YES	10	H A G T L	9	3	40	2	NO	NO	NO	A +ve	Negative	1% GBHC	7	3	20	2	5	2	10	1	6	2	6	1	NIL	MODERATE	NIL
32	BOOPATHY	43	M	135637	U	LABOURER	4	3	4	NO	21	H G T L	6	2	25	2	yes	NO	NO	A+ve	positive	5% Permethrin	3	1	10	1	2	1	4	1	1	0	0	0	NIL	GOOD	NIL
33	VINITHA	11	F	123585	R	STUDENT	4	2	4	YES	8	H A G T L	9	3	45	2	NO	TINEA	NO	O +ve	Negative	0.5% Ivermectin	2	1	20	2	0	0	0	0	0	0	0	0	NIL	GOOD	NIL
34	KAMALA	38	F	185073	U	LABOURER	5	2	5	YES	19	H A G T L	10	3	54	3	NO	NO	NO	B+ve	Negative	1% GBHC	7	3	30	2	5	2	20	2	6	2	12	2	NIL	MILD	NIL
35	MANIMARAN	34	M	153467	U	LABOURER	5	1	4	YES	20	H G T L	9	3	52	3	YES	NO	YES	A+ve	Negative	5% Permethrin	7	3	28	2	5	2	14	2	2	1	4	1	NIL	MODERATE	NIL
36	VASANTHI	24	F	157854	U	LABOURER	5	1	3	YES	22	H A G T	8	3	54	3	NO	NO	NO	O +ve	Negative	0.5% Ivermectin	4	2	20	2	1	1	2	1	0	0	0	0	NIL	GOOD	NIL
37	KALAI	10	F	163894	R	STUDENT	3	1	4	YES	7	H A G T L	10	3	40	2	NO	NO	NO	O +ve	Negative	1% GBHC	8	3	33	2	6	2	25	2	6	2	11	2	NIL	MILD	NIL
38	ROSY	34	F	136421	U	LABOURER	4	1	4	YES	21	H A G T L	10	3	46	2	YES	NO	NO	O +ve	Negative	5% Permethrin	10	3	26	2	6	2	14	2	2	1	3	1	NIL	MODERATE	NIL
39	JOHN	46	M	1906785	U	LABOURER	5	2	5	YES	20	H A G T L	9	3	52	3	YES	NO	YES	A+ve	Negative	0.5% Ivermectin	3	1	15	2	1	1	0	0	0	0	0	0	NIL	GOOD	NIL
40	VIMALA	34	F	128956	R	LABOURER	4	3	4	NO	18	H G T L	10	3	48	2	NO	NO	NO	B+ve	Negative	1% GBHC	7	3	32	2	5	2	22	2	5	2	10	1	NIL	MODERATE	PRESENT
41	RAJA	33	M	120364	U	LABOURER	5	1	2	YES	17	H A G T	9	3	40	2	NO	NO	NO	O +ve	Negative	5% Permethrin	9	3	24	2	6	2	11	2	2	1	2	1	NIL	MODERATE	NIL
42	SAVITHA	30	F	108231	U	LABOURER	4	1	3	YES	14	H A G T L	9	3	36	2	YES	NO	NO	B+ve	Negative	0.5% Ivermectin	3	1	10	1	1	1	0	0	0	0	0	0	NIL	GOOD	NIL
43	SARANYA	18	F	25431	R	STUDENT	3	1	4	YES	10	H A G T L	6	2	35	2	NO	NO	NO	A+ve	Negative	1% GBHC	5	2	25	2	4	2	15	2	3	1	8	1	NIL	MODERATE	NIL
44	PONRAJ	51	M	27342	U	LABOURER	4	3	4	NO	20	H G T L	9	3	36	2	NO	NO	NO	O +ve	Negative	5% Permethrin	9	3	20	2	6	2	10	1	2	1	4	1	NIL	MODERATE	NIL
45	JOSEPH	38	M	36872	U	LABOURER	4	3	4	NO	23	H A G T	8	3	54	3	NO	TINEA	NO	O +ve	Negative	0.5% Ivermectin	2	1	16	2	1	1	0	0	0	0	0	0	NIL	MODERATE	NIL
46	KOKILA	21	F	126831	R	STUDENT	3	1	4	YES	10	H A G T L	6	2	22	2	NO	NO	NO	O +ve	Negative	1% GBHC	5	2	15	2	4	2	10	1	3	1	5	1	NIL	MODERATE	NIL
47	PRAGADISH	17	M	125637	U	STUDENT	4	1	3	YES	8	H A G T L	9	3	52	3	NO	NO	NO	A+ve	Negative	5% Permethrin	6	2	28	2	4	2	12	2	2	1	4	1	NIL	MODERATE	PRESENT
48	SHANKARI	39	F	167829	U	HOUSEWIFE	5	2	5	YES	22	H G T L	10	3	30	2	NO	TINEA	NO	B+ve	Negative	0.5% Ivermectin	3	1	10	1	1	1	0	0	0	0	0	0	NIL	GOOD	NIL
49	UMA	33	F	89674	R	HOUSEWIFE	5	1	3	YES	21	H A G T	10	3	30	2	NO	NO	NO	B+ve	positive	1% GBHC	9	3	25	2	6	2	19	2	5	2	16	2	NIL	MILD	NIL
50	SELVARAJ	43	M	56371	U	LABOURER	5	1	4	YES	20	H A G T L	9	3	44	2	NO	NO	NO	A+ve	Negative	5% Permethrin	10	3	25	2	6	2	12	2	2	1	2	1	NIL	MODERATE	NIL
51	KUMAR	28	M	67302	U	LABOURER	5	1	3	YES	23	H A G T L	9	3	56	3	NO	NO	NO	B+ve	Negative	0.5% Ivermectin	4	2	22	2	1	1	2	1	0	0	0	0	NIL	GOOD	NIL
52	SAROJA	44	F	67249	R	HOUSEWIFE	3	2	4	NO	21	H G T L	10	3	40	2	NO	NO	NO	B+ve	Negative	1% GBHC	7	3	22	2	6	2	12	2	5	1	5	1	NIL	MODERATE	NIL
53	KARTHIK	18	M	156281	U	STUDENT	4	2	5	YES	10	H A G T	9	3	48	2	NO	NO	NO	A+ve	Negative	5% Permethrin	10	3	30	2	6	2	16	2	1	1	0	0	NIL	GOOD	NIL
54	KANTHA	50	F	167981	U	LABOURER	5	1	4	YES	18	H A G T L	9	3	38	2	YES	NO	NO	O +ve	Negative	0.5% Ivermectin	3	1	13	1	1	1	1	1	0	0	0	0	NIL	GOOD	NIL
55	VIJAYALAKSHMI	48	F	98641	U	HOUSEWIFE	3	3	4	NO	15	H A G T L	10	3	48	2	NO	NO	NO	O +ve	Negative	1% GBHC	7	3	32	2	5	2	22	2	5	1	5	1	NIL	MODERATE	NIL
56	NAVEEN	12	M	92451	R	STUDENT	4	1	3	YES	8	H G T L	9	3	36	2	NO	NO	NO	A+ve	Negative	5% Permethrin	9	3	21	2	4	2	16	2	2	1	3	1	NIL	MODERATE	NIL
57	NIVEDITA	10	F	56182	U	STUDENT	3	1	4	YES	10	H A G T	8	3	48	2	NO	NO	NO	B+ve	Negative	0.5% Ivermectin	3	1	12	1	1	1	2	1	0	0	0	0	NIL	MODERATE	NIL

58	LAKSHMI	39	F	72312	U	HOUSEWIFE	5	1	4	YES	16	H A G T L	10	3	40	2	NO	NO	NO	O +ve	Negative	1% GBHC	7	3	25	2	5	2	12	2	2	2	6	1	NIL	MILD	PRESENT
59	SAROJA	41	F	23515	U	HOUSEWIFE	5	3	4	NO	18	H A G T L	9	3	40	2	NO	NO	NO	B+ve	Negative	5% Permethrin	7	3	22	2	4	2	14	2	1	1	4	1	NIL	MODERATE	NIL
60	VIMAL	12	M	25612	R	STUDENT	4	1	4	YES	8	H G T L	9	3	28	2	NO	NO	NO	B+ve	Negative	0.5% Ivermectin	3	1	10	1	1	1	0	0	0	0	0	0	NIL	GOOD	NIL
61	VENUGOPAL	31	M	12526	U	LABOURER	5	1	4	YES	18	H A G T L	10	3	27	2	NO	TINEA	NO	A+ve	Negative	1% GBHC	6	2	18	2	4	2	10	1	2	1	5	1	NIL	MODERATE	NIL
62	GAYATHRI	21	F	12643	U	STUDENT	5	1	3	YES	14	H A G T L	9	3	42	2	NO	NO	NO	B+ve	Negative	5% Permethrin	6	2	23	2	4	2	12	2	1	1	5	1	NIL	MODERATE	NIL
63	RAJA	20	M	`2461	R	LABOURER	4	1	2	NO	15	H G T L	10	3	30	2	NO	NO	NO	O +ve	Negative	0.5% Ivermectin	3	1	10	1	1	1	2	1	0	0	0	0	NIL	GOOD	NIL
64	MANI	43	M	125789	U	LABOURER	5	1	4	YES	19	H A G T	10	3	26	2	YES	NO	NO	B+ve	positive	1% GBHC	7	3	18	2	5	2	10	1	3	1	2	1	NIL	gooD	NIL
65	PUSHPA	44	F	122452	U	HOUSEWIFE	4	3	4	NO	21	H A G T L	9	3	46	2	NO	NO	NO	A+ve	Negative	5% Permethrin	10	3	27	2	4	2	14	2	1	1	2	1	NIL	MODERATE	NIL
66	RANJITA	17	F	122351	R	STUDENT	3	1	3	YES	18	H G T L	9	3	46	2	NO	NO	NO	O +ve	Negative	0.5% Ivermectin	2	1	12	2	1	1	0	0	0	0	0	0	NIL	GOOD	NIL
67	PRABHU	30	M	146124	U	LABOURER	5	1	3	YES	20	H A G T L	9	3	38	2	NO	NO	NO	A+ve	Negative	1% GBHC	6	2	24	2	4	2	12	2	3	1	3	1	NIL	MODERATE	NIL
68	NIRMALA	32	F	135232	U	HOUSEWIFE	4	3	4	NO	19	H A G T	9	3	36	2	yes	NO	NO	B+ve	Negative	5% Permethrin	10	3	20	2	4	2	10	1	1	1	0	0	NIL	MODERATE	NIL
69	GAYATHRI	33	F	122352	R	LABOURER	5	1	4	YES	16	H A G T L	6	2	20	2	NO	TINEA	NO	B+ve	Negative	0.5% Ivermectin	2	1	6	1	1	1	0	0	0	0	0	0	NIL	MODERATE	NIL
70	KARTHIK	21	M	135124	U	LABOURER	4	1	5	YES	14	H A G T L	6	2	22	2	NO	NO	NO	O +ve	Negative	1% GBHC	5	2	12	2	4	2	6	1	5	1	2	1	NIL	MODERATE	NIL
71	KOMALA	12	F	152351	R	STUDENT	3	1	4	YES	12	H A G T L	9	3	48	2	NO	NO	NO	A+ve	Negative	5% Permethrin	10	3	30	2	4	2	16	2	1	1	2	1	NIL	MODERATE	NIL
72	MITHRAN	14	M	167234	U	STUDENT	4	1	4	YES	10	H A G T	9	3	40	2	NO	NO	NO	B-ve	Negative	0.5% Ivermectin	4	2	12	2	1	1	2	1	0	0	0	0	NIL	GOOD	NIL
73	SARAN	12	M	1873462	U	STUDENT	5	1	3	YES	10	H A G T L	9	3	40	2	NO	NO	NO	A+ve	Negative	1% GBHC	7	3	25	2	5	2	18	2	2	1	6	1	NIL	MODERATE	NIL
74	THARUN	10	M	130967	R	STUDENT	4	1	4	YES	7	H G T L	9	3	26	2	YES	NO	NO	O +ve	Negative	5% Permethrin	9	3	14	2	4	2	10	1	1	1	2	1	NIL	MODERATE	NIL
75	MANOHAR	32	M	135233	U	LABOURER	5	1	4	YES	12	H A G T L	10	3	44	2	YES	NO	NO	O +ve	Negative	0.5% Ivermectin	3	1	10	1	1	1	0	0	0	0	0	0	NIL	GOOD	NIL
76	SUBILASH	17	M	24621	U	STUDENT	4	1	3	YES	14	H A G T L	9	3	22	2	NO	NO	NO	A+ve	Negative	1% GBHC	8	3	15	2	6	2	10	1	1	1	0	0	NIL	GOOD	PRESENT
77	MUTHULAKSHMI	50	F	123562	R	HOUSEWIFE	5	3	4	NO	20	H A G T	9	3	44	2	NO	NO	NO	B+ve	Negative	5% Permethrin	9	3	26	2	6	2	10	1	0	0	0	0	NIL	GOOD	NIL
78	SUNDARI	39	F	84321	U	HOUSEWIFE	5	3	3	NO	18	H A G T L	8	3	34	2	YES	NO	NO	A-ve	Negative	0.5% Ivermectin	2	1	12	2	1	1	2	1	0	0	0	0	NIL	GOOD	NIL
79	MOHIDEEN RISHVI	44	M	72344	U	LABOURER	4	1	4	YES	15	H A G T L	10	3	56	3	NO	NO	NO	AB+ve	positive	1% GBHC	8	3	43	2	7	3	30	2	5	2	11	2	NIL	MILD	NIL
80	KANNIGA	18	F	125743	U	STUDENT	4	1	4	YES	7	H G T L	9	3	25	2	NO	TINEA	NO	B+ve	Negative	5% Permethrin	5	2	14	2	2	1	2	1	0	0	0	0	NIL	GOOD	PRESENT
81	DHANALAKSHMI	48	F	146433	R	HOUSEWIFE	5	1	2	NO	15	H A G T L	9	3	52	3	NO	NO	NO	O+ve	Negative	0.5% Ivermectin	2	1	18	2	1	1	0	0	0	0	0	0	NIL	GOOD	NIL
82	PRATHYUSHA	10	F	178978	U	STUDENT	3	1	3	YES	15	H A G T	10	3	35	2	NO	NO	NO	B-ve	Negative	1% GBHC	8	3	25	2	5	2	13	2	3	1	5	1	NIL	MODERATE	NIL
83	KANNAGI	28	F	189490	U	HOUSEWIFE	3	1	2	YES	14	H A G T L	6	2	26	2	NO	NO	NO	B+ve	Negative	5% Permethrin	6	1	16	2	3	1	10	1	0	0	0	0	NIL	GOOD	NIL
84	SEKARAN	40	M	28970	U	LABOURER	4	1	3	YES	12	H A G T L	6	2	24	2	yes	NO	NO	O+ve	positive	0.5% Ivermectin	8	3	10	1	4	2	0	0	2	2	1	1	NIL	moderate	NIL
85	LAKSHMI	52	F	68903	R	LABOURER	4	3	4	NO	14	H G T L	10	3	54	3	NO	NO	NO	A-ve	Negative	1% GBHC	8	3	45	2	7	3	24	2	4	2	11	2	NIL	MILD	NIL
86	VIJAYAKUMARI	42	F	159822	U	HOUSEWIFE	4	1	3	YES	14	H A G T L	9	3	34	2	NO	NO	NO	O+ve	Negative	5% Permethrin	8	3	18	2	3	1	5	1	0	0	0	0	NIL	GOOD	NIL
87	PRANAV	11	M	28992	U	STUDENT	4	1	3	YES	8	H A G T	9	3	52	3	YES	NO	NO	B+ve	Negative	0.5% Ivermectin	2	1	22	2	1	1	0	0	0	0	0	0	NIL	GOOD	NIL
88	MARTEN	50	M	97221	R	LABOURER	4	1	2	NO	7	H G T L	10	3	25	2	NO	NO	NO	A+ve	positive	1% GBHC	8	3	15	2	6	2	10	1	3	1	2	1	NIL	MODERATE	NIL
89	VIMALA	51	F	125123	U	HOUSEWIFE	4	1	2	NO	7	H A G T L	9	3	54	3	NO	NO	NO	B+ve	Negative	5% Permethrin	10	3	30	2	6	2	16	2	0	1	2	1	NIL	MODERATE	NIL
90	PRAVEEN	23	M	135129	R	LABOURER	4	1	5	YES	10	H A G T L	6	2	30	2	NO	NO	NO	AB-ve	Negative	0.5% Ivermectin	3	1	10	1	1	1	0	0	0	0	0	0	NIL	GOOD	NIL